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Additional Information
For indications for use, contraindications, warnings, precautions, adverse effects pertinent to prescribing the Precision™ Spinal Cord Stimulation System for pain therapy, and limited warranty, refer to the appropriate DFU as listed on your BS Reference Guide.

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*Applicable after installation of Bionic Navigator 1.2 (Software version 9028287-002)
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Section 1 Clinician Programmer

Note: The word “Clinician Programmer” or “CP” refers to the Toshiba notebook and ASUS or Surface Pro 3 Tablets.

Adjusting CP Date and Time

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 click Ok to confirm changes.

Text Entry

Figure 1: Toshiba

Figure 2 - ASUS and Surface Pro 3 Tablets

Description

Text entry options are provided for ease of data entry. There are three methods for entering patient Profile data and patient Notes using the CP keyboard and Tablet PC Input Panel feature. The text entry icon for the Tablet PC Input feature may be located on the Windows Task Bar.

Access/Exit

- To access the [Windows Task Bar], move the pen over the very bottom of the screen. Click the keypad [Icon].
- To exit any text entry tool, click the [X] on the right-hand corner of the tool.

Additional Information

- See Toshiba Portege 3500, M200, or M400 Tablet PC Series Manuals at www.toshiba.com for additional instructions.
- See ASUS Eee Slate B121 manuals at www.asus.com for additional instructions.
- See Surface Pro 3 manuals at www.microsoft.com for additional instructions.
- See the Set-up and Communication section below for more information.

Set-Up and Communication

CP Keyboard

The CP Keyboard is used to enter patient information using the conventional method.

Tablet PC Input Panel

The Tablet PC Input Panel is a touchable keyboard and writable window.

- Place the cursor on the [Text field]. Enter the appropriate letters or numbers on the keypad or write the text in the text input window. To erase information, click Backspace.

Description

The Clinician’s Programmer (CP) communicates with the stimulator using an infrared link to the Remote Control. Programs can be loaded to the CP for previewing, activating and changing stimulation patterns. Stimulation programs can also be saved to the Remote Control.

Set-up and Operation

Caution: The CP is not equipment for the patient environment as defined by IEC 60601-1. Neither the CP nor the person programming the CP should be in contact with the patient while programming.

- Power [ON] the CP to display the Neuromodulation desktop.
- Select the Bionic Navigator icon to boot up the Bionic Navigator 1.2 Software.

1. Enter the [Clinician’s screen] on the Remote Control by simultaneously selecting the SEL 1 and SEL 2 buttons.
2. Enter the [Physician Code - ABC], or
3. Enter the [Clinician’s screen] on the Remote Control by pressing both the Area \( \text{F} \) and Program \( \text{P} \) buttons simultaneously.
4. Select “CP Mode”.
   • When the Remote Control displays [CP Ready], face the IR window at the top of the Remote Control towards the IR extension.
   • Position the patient within two feet of the Remote Control to ensure communication with the implantable stimulator.
   
   Maintain a clear path between the IR extension attached to the Clinician’s Programmer and the Remote Control IR window.

Using the Patient Controller (Joystick)
• When creating a paresthesia-based program, adjust the stimulation level until it is comfortable by pressing the up and down arrow buttons. To stop or turn off stimulation immediately, press the [OFF] button.
• Once the patient is receiving therapy, navigate using the direction keys to locate a good area.
• Press the red button once you have found a good location. Pressing the red button has the same effect as clicking the “Mark” key on the tablet screen.
• Continue or repeat the process until the patient is satisfied. To provide therapy without having the patient feel stimulation, identify the stimulation level at which sensations are felt and adjust amplitude downwards by pressing the down arrow button, and adjust rate and pulse width as necessary.

Additional information
• A message will be displayed on the Clinician Programmer if the communication range is not satisfactory.

Sync Data

• To transfer data between database and Clinic Card press [Sync Data] from any screen.
• Click [Select All], or click the box preceding an individual patient’s name.
  To delete records, click the desired [name], then click [delete].

Additional Information
• If a discrepancy is found in the patient profile information select which information to use, or skip this option.
• The “Backup Card” located in the removable card slot should never be removed except by the Boston Scientific Representative.

System

Description
The system screen is used to view or change clinic preferences for default settings of pulse width, rate, ramp time, patient access lockouts, and Remote Control language. The screen also provides access to backing up Database and Logs, adding and modifying leads, estimating relative lead positions, and stimulator information.

Access/Exit
• To access “System,” select [System] at the top right-hand corner of the screen, make adjustments.
• To exit, click [OK] to change parameters or [Cancel].

System
• Click, [System] to check stimulator and Remote Control information regarding default settings for pulse width, rate, ramp time and remote language.
  To create a compressed file of database and logs, click [Backup Data/Logs].
  To add, modify, or import information regarding a lead, click [Add Lead].
  To check stimulator and Remote Control information regarding identification, type, version, battery voltage and status, click [System Info].
  To display relative lead positions, click [EGL Scan].

Backup Data/Logs
To manually create a separate compressed file of database and logs.

• Insert [Removable media] to copy database and logs.
  - This removable media should not be labeled “CLINIC”

Installing New Clinic Card
• Insert removable media labeled “CLINIC”.
  
  After the initial insertion of the removable media, every time the patient session is closed (for example by clicking on [START]),
• Click on **Backup Data/Logs** button
  - *Database is successfully copied when message appears*
• Click [OK] to exit.

**Add Lead**

• To add, modify, or import a lead, click **[Add Lead]**, then enter all required information and a valid **Key Code**.
  - *Contact a Boston Scientific representative for the key code.*
• Click [OK] to save information or [Cancel] to exit without saving.
• To import lead information from a file, click on **[Import]**.

**System Information**

• **System Information** is only available when a stimulator is connected to the **Clinician's Programmer**.
• Click, **[System Info]** to check stimulator and **Remote Control** information regarding identification, type, version, battery voltage and status. Click [OK] to exit.

**EGL Scan™**

The **EGL Scan** image is a display of relative lead positions.

• Click **[EGL Scan]** to access image.
  - **EGL Scan** is available only if supported by the stimulator.
  - **EGL Scan** requires a patch electrode for an external trial stimulator (ETS).
• Optionally, select the number of samples and the amplitude to be used for **EGL Scan** before initiating **EGL Scan**.
• To print **EGL Scan image**, click [Print] or [Cancel] to exit.

**Additional Information**

• To change patient settings use **[Patient Options]**.
Section 2  Pain Coverage and VAS Scores

Graphic Module

Description
The Graphic Module is used to identify both pain and pain coverage areas using a visual representation of anatomical coverage areas in relationship to the patient. Pain areas can be entered on the Patient Profile screen and pain coverage can be entered in the programming screens.

Access/Exit
• To access the “Graphic Module,” select [Profile] or [Manual] or progress through the Navigator.
• To save information and exit, select [Finish] or [Next].

Entering Pain
• Select [Profile].
  - Pain (Orange) regions can only be entered in the Patient Profile screen.
  - Click on Graphic Module [Regions] to indicate pain locations.

Entering Pain Coverage
• Select [Manual] or advance to the Navigator’s “Coverage Area” Screen.
  - Pain coverage is entered only on programming screens.
  - Click on one or more [Regions] of the “Graphic Module” to indicate locations where pain is covered.
    - Blue denotes pain coverage and is blended over pain areas to denote overlap (Purple).

Resolution (RES)
• Click [RES] to toggle between low and high resolution mapping.

View
• Click [VIEW] to toggle from front to back on the Graphic Module.

Additional Information
• Pain coverage is tied to selected coverage areas.
• Entering pain coverage for each programmed coverage area will automatically name the area in the Remote Control.
• Click the VAS button to document a Visual Analog Scale.

OR Mapping

Description
The OR Mapping screen is used to assess lead position and therapy. OR Mapping allows both Electronic Trolling and manual electrode selection. Electronic Trolling (E-Troll) is a quick way to sweep the electrode array by moving the cathode in bipolar stimulation.

Model Drop-down List
The model drop-down list is used to select the type of lead that is being used. The default selection is the Boston Scientific’s SC-2108-xx Linear lead.

Access/Exit
• To access “OR Mapping,” select [OR Mapping] in the lower left-hand corner of any screen.
• To exit, select [Finish].

E-Troll
E-Troll activation enables trolling using the up, down, left and right arrows to move the stimulation focus. Any electrode can be selected to initiate Trolling. Manual electrode polarity configuration is disabled when E-Troll is on.

• Press the [E-Troll] button on.
• [Adjust amplitude] to a comfortable level.
• Use the up, down, left and right trolling arrows to [direct stimulation].
• Click on any electrode to jump to a desired target on the lead arrays. Stimulation will stop, and amplitude should be increased to continue trolling.
• [Adjust the amplitude, rate and pulse width] by clicking the appropriate arrow.
  - Amplitude may need to be periodically adjusted during trolling to account for fluctuations in intensity perception.
• Click, and/or click and hold the amplitude up and down arrows to increment / decrement amplitude step size. Amplitude step size will vary depending on arrow selection. Double arrows adjust by 3 step increments/decrements. Single arrows adjust by single step increments/decrements.

Manual Electrode Selection
Manual electrode selection is enabled when E-Troll is off. Electrode configurations are selectable.

• Click [Electrodes] to assign polarity.
  - Once for (+) anode
  - Twice for (-) cathode
  - Three times for (0) polarity
• [Adjust the amplitude, rate, and pulse width] by clicking the appropriate arrows.
• Selecting additional electrodes while stimulating causes stimulation to be turned off. Adjust amplitude to a comfortable level.
Additional Information

- Impedance measurements can be repeatedly taken by pressing the Ω button.
- An X on the impedance measurement screen indicates out of range electrode measurements or electrodes that are not connected. If the electrodes are reconnected or the impedance measurements fall within the acceptable range, repeating the impedance measurement will clear the X.

VAS

Description
The VAS screen documents a patient's current level of pain with either the stimulation “On” or “Off.” Bionic Navigator 1.2 Software will note whether stimulation is “On” or “Off” at the time the score is recorded. The last score will be displayed in the VAS access button; red denoting stimulation off (without therapy) and blue denoting stimulation on (with therapy). A comparative report can be created if VAS scores are recorded with both stimulation on and stimulation off.

Access/Exit
- To access the Visual Analog Scale, select VAS on Profile, Manual, Navigator or Remote.
- To exit VAS, click [OK] to record information or [Cancel].

Scoring
- Slide or click on the pointer to the [Numerical Point] on the screen that reflects the patient’s current level of pain with stimulation [On] or [Off].
  - A score of 0 is equivalent to no pain.
  - A score 10 is equivalent to the worst pain possible.

Additional Information
- Displayed VAS corresponds to last entered VAS scores for the session.
- Click Reports to view VAS history.
- Last VAS score taken in a session is stored in the database.
Section 3  Patient Files

Case History

Description
The Case History displays chronologically dated patient visits.

Access/Exit
- To access “Case History” information, select [Profile], then [Case History].
- To exit, select [OK].

Additional Information
- The case history can also be viewed and printed from Reports.
- Click Profile to enter Notes.
- Click Start to access “Reason for Visit.”

Getting Started

Description
The Start Screen is used to begin a patient session. Three programming modes are selectable from this screen: OR Mapping, Manual, and Navigator. The programming option buttons (located at the bottom of each screen) provide programming to suit the clinical environment. The functional buttons (located at the top of each screen) provide access to patient file information and other system features.

Access/Exit
- The “Start Screen” is opened when the Bionic Navigator 1.2 Software is started, or [Start] is selected from the top right-hand corner of any screen.
- To exit, select [any button] located on the screen or close Bionic Navigator.

Patient Name
- To enter patient information, select the down arrow in the [Patient Name] field, then select an appropriate patient from the alphabetized list, or select a [New Patient] which will automatically display Profile.

Reason for Visit
- Click on the [Reason for Visit] field, then select an appropriate visit entry.

Additional Information
- Click OR Mapping for confirmation of lead placement, during surgery.
- Click Manual for research and manual programming.
- Click Navigator to dynamically fit patient.
- Click Remote to proceed to patient programs stored on the Remote Control.
- Click Reports to customize a patient or clinic report.
- Click Start to return to the Start Screen from other screens.
- Click Help to receive additional information about the Bionic Navigator 1.2 Software.
- Click Config to enter lead information and view device hardware information.
- Click Profile to enter or view patient information.
- Click Sync Data to transfer data to and from removable memory.

Notes

Description
The Notes screen is used to enter relevant information, which is stored and can be chronologically viewed in the patient’s case history.

Access/Exit
- To access “Notes,” select Profile, then [Notes].
  - Enter patient notes by using the CP keyboard or either of the Tablet PC Input Panel options.
- To exit, select [OK] or [Cancel] to return to the Profile screen.

Additional Information
- Current notes are editable.
- Past notes are read only.
- Click Case History to view past notes or go to Reports.

Patient Profile
Description
The Profile screen is an area where the user enters or edits information required to generate or update a patient record. This screen allows the user to enter, view, or edit Patient Identification Information, Patient Contact Information, Pain Areas, a VAS score, Notes and Case History Information.

Access
- To access “Patient Profile,” select [Profile] in the upper right-hand corner of any screen.
- To enter a new patient from the Start Screen, click the drop-down menu from the [patient name] field, and select [new patient] from the list.
- This will automatically forward you to the Profile Screen to enter new patient information, and will return you to the Start Screen when complete.
- To view or edit an existing patient file from the Start Screen, click the drop-down menu from the [Patient Name] field, and select patient from the list. Then click Profile in the upper right-hand corner of the Start Screen.

Entering and Editing Patient Information
1. Enter information using the Text Entry, CP Keyboard or Tablet PC Input Panel.
2. Click [Finish] to save information and return to the “Start Screen.”

Additional Information
- Patient name and birth date are required fields.
- Click on the Graphic Module to identify and document the patient’s pain area.
- Click VAS to document a pain intensity level, then select OK.
- Click on Notes to enter comments into the patient’s file.
- Click on Case History to chronologically view patient file information, including the visit history and notes.

Reports

Description
The Report screen is used to create a patient or clinic report. By selecting various options for individual patients or groups, the user can create, view, print, export or close database information. Reports can be generated by type, and each report can be customized through sorting filters.

Access/Exit
- To access “Reports,” select [Reports] in the top right-hand corner of any screen.
- To exit, select [Finish].

Print and Export
- Select a [Report Type]:
  - Patient Information
  - Patient information, clinic information, hardware information, stimulation settings, profile information, battery usage, case history, and patient notes for various time intervals.
  - Patient List
  - Last visit, serial number, implant date and physician.
  - Clinical Outcomes
  - Implant, last visit, physician, diagnosis, percentages and means, implant duration, mean age, replacements, explants, revisions, and average VAS scores.
  - Clinic Activity
  - Last visit, physician and patient follow-ups. May include reprogrammings, trials, lead implants, total patients, average durations, and total durations.
  - Generic Report
  - Programs, threshold measurement, impedances, battery usage profile, program usage profile, patient history, lead configuration. Parameters include: patient drop-down list (select by patient name), from date, to date and a checkbox to list result in ascending/descending order.
- Click on [Qualifiers] to sort.
- Click [Create a Report] then, select print or export.

Note: When printing without a printer set-up, the report will be saved to a file. The Save As dialog box may be displayed behind the current open window and may not be immediately accessible. You can access the Save As dialog box through the taskbar button or, you can press Alt+Tab to switch the focus to the dialog box.
Section 4 Patient Hardware

Battery Status

![Battery Status Screen]

Description
The Battery Status screen graphically illustrates the battery level (Full, Medium, Low) of the stimulator. An estimate for charging the implant is provided. Charging will vary with use.

Access/Exit
- To access “Battery Status,” select [Remote] on the lower right-hand corner of any screen, then click [Battery].
- To return to the Remote Control screen, click [OK].

Measure Battery Voltage
- Click [Measure] to obtain current stimulator voltage value and level.

Additional Information
- The rechargeable implant battery should provide at least five years of service. In many cases, the implant battery may provide at least 25 years of service. Battery life is dependent on the stimulation settings and conditions.
- Charging directions are estimated based on active Remote Control settings in a 24-hour period.
- See the Precision™ Spinal Cord Stimulator Clinician Manual for charging times.
- Charge the implantable stimulator until a beeping tone is heard.
- Go to Reports to view battery use information or to print.

Hardware Configuration Summary

![Hardware Configuration Summary Screen]

Description
The Hardware Configuration Summary screen reflects device hardware information and lead orientation. Stimulator and Remote Control model and serial numbers are automatically detected and recorded while lead information (after entered in the lead configuration series) is displayed. Once information is entered into the patient’s file, this screen is available for verifying and modifying lead information.

Access/Exit
- To access “Hardware Configuration Summary,” select [Config] button in the upper right-hand corner of any screen.

  If lead information has not been entered, the information will be requested before the Hardware Configuration Summary screen is displayed.

- To return to the Start Screen, select [Finish].

Modifying Lead Configuration

Lead information includes configuration, orientation and model numbers, which can be modified or updated at any time.

- Select [Modify] to return to the first screen of the Lead Configuration series.
- Advance through the Lead Configuration screens and enter the new information by clicking the appropriate selections.

Change Lead-Stimulator Connections

“Connections” relates to the 1-L and 2-R ports on the Stimulator. If left and right leads were inadvertently reversed, programming of left or right may be opposite to physiological left or right.

- Click [Connections] to switch or correct lead connections to the Stimulator.
- Select [SWAP] to change the connection of the leads to the Stimulator ports, and [OK] to save.

Update Lead Location

- Click on the Vertebral control to enter or update the lead location.
- Click [OK] to save or [Cancel] to ignore the modifications, in the Connections Screen.

Additional Information:
- Hardware Configuration Summary is only accessible after entering lead configuration information.
- Click Ω in Hardware Configuration Summary to access lead impedance.

Leads (Config)
Description
Configuration is a series of three screens: Lead Model Selection, Lead Configuration, and Lead Orientation. All screens are used for entering and modifying lead and device hardware information for patient records and Navigator programming.

Access/Exit
- To access “Lead Configuration,” select the [Config] button in the top right-hand corner of any screen. If lead information has been previously entered, the Hardware Configuration Summary screen will be displayed. To change information, select Modify.
- To exit screen after entering all configuration information, select [Finish].

Lead Model
The Lead Model screen documents the model number of the implanted lead(s).
- Select the [model number] from the drop down menu. Based on the first lead selected, the list of available leads for the second selection will vary.
- Click [Next] to continue. For two lead selection, Lead Configuration Screen will be displayed. For single lead selection, Lead Orientation Screen will be displayed.

Entering Lead Configuration
The Lead Configuration screen is required and only visible for indicating configurations of more than one implanted lead.
- Click on the [Drawing] of the most appropriate lead configuration.
- Click [Next] to proceed to Lead Orientation.

Lead Orientation
The Lead Orientation screen indicates the implantable lead direction and the vertebral position of the lead.
- If the lead or leads are retrograde, click the [Retrograde] box to the right.
- Click on the [Vertebral Control] to document or update the vertebral position of the lead.

Select [Next] to proceed to Hardware Configuration Summary, and then press [Finish] to return to the Start screen.

Additional Information
- The Hardware Configuration Summary is a screen, which summarizes lead position, model numbers, and implanted hardware.
- Click [Modify] from the Hardware Configuration Summary screen to modify previously entered lead configuration information.
- Click [Connections] to modify lead connection to the IPG.
- Click the [Ω] button to access lead impedance.

Links and Resets

Description
Linking is the Boston Scientific term for programming the Remote Control to communicate with a specific stimulator (temporary/trial or permanent/IPG), and determining the therapy program the devices will share. Resetting describes the process of clearing previously stored programs from a clinic Remote Control and/or Trial Stimulator.

Operation
- A new Remote Control removed from a Physician Trial Kit may be linked to the new Trial Stimulator, loaded with a preliminary “program” through the Clinician Programmer during the trial surgery and delivered to the trial patient.
- A Remote Control linked to Trial Stimulator A but kept at the clinic must be de-linked from the Trial Stimulator A before it can be used with Trial Stimulator B or with an IPG while linking with the new device, the remote will prompt your decision concerning how to reset the equipment.

Remote Control
Linking an unlinked Remote Control will automatically display it’s status when any button is pressed. Press Program P on the remote to initiate a link with a stimulator within telemetry range:
- The remote will identify the targeted device and determine the stimulator’s programmed status.
- The remote will compare its programmed status against that of the stimulator and prompt you to choose either program set, if applicable.
- If the preferred program set is the Remote Control programs, you will need to enter the clinician password before downloading programs from the remote.
- If neither the remote or the stimulator has stored programs, device linking is immediate.
De-linking
Press and hold the **Area** and **Program** buttons on the **Remote Control** for approximately three seconds to access the **Enter Clinician Options** screen.

- From the **Enter Clinician Options** screen, select “To Clear Link”.
- At the prompt, enter the **clinician password**.

*The unlinked **Remote Control** will immediately display its status. You may re-link immediately, or press **P** to postpone linking.*

Remote Control
Link or de-link by entering the [Physician Code - ABC] on the **Remote Control**, and select [Reset].

- Select [Change Patient] to clear all programs and settings.

*For a new patient trial, or when using a clinic remote for different patients, always clear programs and settings.*

Select [Change Link] to use a programmed **Remote Control** for a patient with new permanent/IPG.

Resets from the Clinician’s Programmer
- Plug the **IR Dongle/USB Extension** into the USB port and slip **Remote Control** into the slip pouch.
- Position the IR window of the **Remote Control** in-line with the IR window of the dongle.
- Enter the [Clinician’s screen] if appropriate on the **Remote Control**.
- A message “**CP Ready**” will be displayed.

System

![System Screen](image)

**Description**
The **System** screen is used to view or change **clinic preferences** for default settings of **pulse width, rate, ramp time, patient access lockouts, and Remote Control language**. The screen also provides access to backing up **Database** and **Logs**, adding and modifying leads, estimating relative lead positions, and stimulator information.

**Access/Exit**
- To access “**System**,” select [**System**] at the top right-hand corner of the screen, make adjustments.
- To exit, click [**OK**] to change parameters or [**Cancel**].

**System**
- Click, [**System**] to check stimulator and **Remote Control** information regarding default settings for **pulse width, rate, ramp time and remote language**.

*To create a compressed file of **database** and **logs**, click [**Backup Data/Logs**].

Backup Data/Logs
To create a compressed file of **database** and **logs**.

- Insert [**Removable media**] to copy **database** and **logs**.
  *Removable media should not be labeled “CLINIC.”*
- Click on **Backup Data/Logs** button
  **Database** is successfully copied when message appears.
- Click [**OK**] to exit.

Add Lead
- To add, modify, or import a lead, click [**Add Lead**], then enter all required information and a valid **Key Code**.
  *Contact a Boston Scientific representative for the key code.*
- Click [**OK**] to save information or [**Cancel**] to exit without saving.
- To import lead information from a file, click on [**Import**].

System Information
- **System Information** is only available when a stimulator is connected to the **Clinician’s Programmer**.
- Click, [**System Info**] to check stimulator and **Remote Control** information regarding identification, type, version, battery voltage and status. Click [**OK**] to exit.
**EGL Scan™**

The EGL Scan image is a display of relative lead positions.

- Click [EGL Scan] to access image.
  
  *EGL Scan* is available only if supported by stimulator.
  
  *EGL Scan* requires a patch electrode for an external trial stimulator (ETS).

- Optionally, select the **number of samples** and the **amplitude** to be used for EGL Scan before initiating EGL Scan.

- To print EGL Scan image, click [Print] or [Cancel] to exit.

**Additional Information**

- To change patient settings use [Patient Options].
Section 5  Programming and Patient Fitting

Manual Programming

Description
The Manual Programming screen displays active stimulation settings and allows programming by manual selection of anodes, cathodes, and parameters. Upon entering the Manual screen, the active stimulation settings are displayed.

Access/Exit
• Select [Next] to advance to Remote, where the program can be saved to the Remote Control.
  Areas that have stimulation set to OFF, are cleared from the program.

Programming
Stimulation settings can be programmed for up to four independent coverage areas, creating a program. Electrode parameters and pain coverage maps are displayed for one selected area at a time.

• Click [SEL] to select an Area.
  Once selected, each area can be selectively turned on and off in the area control box.
• Define electrodes for the selected area by clicking on the [desired electrode].
  Click [Electrodes] to assign polarity. Electrode Polarity cycles through OFF, anode (+) and cathode (-).
  Each area must have the same type of configurations (monopolar or multipolar).
• Adjust [Amplitude, Pulse Width and/or Rate] to achieve stimulation for the selected area.
  Amplitude may need to be periodically adjusted during programming to account for fluctuations in intensity perception.
  If more than one Area is programmed rate is limited to be less than or equal to 130 Hz.
• Click or click and hold the amplitude up and down arrows to increment/decrement amplitude. Amplitude step size will vary depending on arrow selection. Double arrows adjust by 3 step increments/decrements. Single arrows adjust by single step increments/decrements.
• If desired, activate the Global button to simultaneously adjust amplitude level for all programmed areas. If the Global button is selected, only amplitude can be adjusted.
  The Global button is automatically selected when multiple areas are active upon entering screen.
• To stop and start all stimulation, use the main [Stimulation Power Button] in the lower left corner.

Pain Coverage
• To enter pain coverage maps for a selected area, click section(s) on the Graphic Module where pain coverage is occurring.
• Area Names
  Click on the Area Name control to enter and modify Area name, or
  Click on [Graphic Module section(s)] to name an area that has not been entered/edited previously.

Additional Information
• Unconnected or broken contacts are displayed with an X.
• Click Reports to print program data.
• Click VAS to enter Visual Analog Score.
• Click System to access/modify default settings for new patients.

Maximum Current Amplitude per Electrode versus Impedance

Navigator Programming

Description
The Navigation process consists of three screens to create a stimulation program. The Navigator is used to define the best stimulation configurations by setting calibration points and steering current fields for up to four independent pain coverage areas.

Access/Exit
• To access “Navigator,” select [Navigator] from the lower right hand corner of any screen.
• To advance through the Navigator process, click [Next] after each screen, then [Finish] after saving the program on the Remote.
• To exit to any other function during the Navigation process, simply press the desired function button.
Navigation Threshold Calibration

Threshold Calibration sets test points for steering current fields. To perform calibration, the user must perform and record both minimum (perception) and maximum (discomfort) stimulation thresholds for preset bipoles. Each preset electrode pair required for steering is represented by a window and automatically advances as each “Min” and “Max” is recorded.

- Increase [amplitude level] until perception is felt, then press [Min].
- Continue to increase [amplitude level] until stimulation is uncomfortable, then press [Max].
- The next bipole will automatically advance. Repeat recording Min and Max thresholds until the required set is complete or until “Next” button appears on the screen.
- Click on the preset where the patient noted the best coverage. To compare stimulation, simply click on each preset and adjust amplitude.
- Click [Next] to advance to the Navigator.

Coverage Areas

The Coverage Area screen allows entry of the pain coverage onto the Graphic Module for the area just navigated. This will provide an anatomical name for identification purposes. Additional coverage areas can be navigated, then combined and assessed on this screen.

- [Enter pain coverage] on the Graphic Module to associate with the selected area.
- Area Names

Click on the Area Name control to enter and modify Area name, or
Click on [Graphic Module section(s)] to name an area that has not been entered/edited previously.

- Adjust amplitude if necessary on Area using the up/down arrow buttons.
- Click [Add Another Area] to return to the Navigator in order to build additional coverage into the program.

This will return the Navigator screen to repeat the process, marking and selecting best coverage for the next target area.

- After Navigating additional areas, [enter pain coverage] for each area, with other areas set to OFF, to clearly associate each pain coverage map with an area.
- [Turn on] and adjust all navigated areas to confirm the program effectiveness, and make any necessary amplitude adjustments.
- Click [X] to delete an area.
- Click [Redo] to modify existing Area.

Redo will display the navigator screen with corresponding Mark selected and with amplitude set for that Mark.
- Click [Next] to advance to Remote Control, and save the newly created stimulation program onto the patient's Stimulator/Remote Control. Areas that have stimulation set to OFF, are cleared from the program.

Additional Information
- Lead Configuration information is required for Navigation.
- Click Manual to view or change stimulation parameters, and repeat the Navigation process.
- The Navigator window represents relative anatomical location of the electrode array/s (leads) over the spinal cord, and the viewer along the bar can be raised inferior and superior, and left and right of the midline. Left and right are only available with dual lead implantation.
- Only one area is navigated at a time, then combined and assessed in the Coverage Area screen.
- Only one preset per lead is displayed in the Calibration Screen.
- Two presets will be displayed for a paddle lead.

Maximum Current Amplitude per Electrode versus Impedance

Access/Exit
- To access “OR Mapping,” select [OR Mapping] in the lower left-hand corner of any screen.
- To exit, select [Finish].

E-Troll
E-Troll activation enables trolling using the up, down, left and right arrows to move the stimulation focus. Any electrode can be selected to initiate Trolling. Manual electrode polarity configuration is disabled when E-Troll is on.

- Press the [E-Troll] button on.
- [Adjust amplitude] to a comfortable level.
- Use the up, down, left and right trolling arrows to [direct stimulation].
- Click on any electrode to jump to a desired target on the lead arrays.
  
  *Stimulation will stop, and amplitude should be increased to continue trolling.*

- [Adjust the amplitude, rate and pulse width] by clicking the appropriate arrow.
  
  *Amplitude may need to be periodically adjusted during trolling to account for fluctuations in intensity perception.*

- Click, and or click and hold the amplitude up and down arrows to increment / decrement amplitude step size. Amplitude step size will vary depending on arrow selection. Double arrows adjust by 3 step increments/decrements. Single arrows adjust by single step increments/decrements.

Manual Electrode Selection
Manual electrode selection is enabled when E-Troll is off. Electrode configurations are selectable.

- Click [Electrodes] to assign polarity.
  - Once for (+) anode
  - Twice for (-) cathode
  - Three times for (0) polarity

- [Adjust the amplitude, rate, and pulse width] by clicking the appropriate arrows.
- Selecting additional electrodes while stimulating causes stimulation to be turned off. Adjust amplitude to a comfortable level.

Additional Information
- Impedance measurements can be repeatedly taken by pressing the Ω button.
- An X on the impedance measurement screen indicates out of range electrode measurements or electrodes that are not connected. If the electrodes are reconnected or the impedance measurements fall within the acceptable range, repeating the impedance measurement will clear the X.

Patient Options

**OR Mapping**

Description
The OR Mapping screen is used to assess lead position and evaluate paresthesia coverage during surgery. OR Mapping allows both Electronic Trolling and manual electrode selection. Electronic Trolling (E-Troll) is a quick way to sweep the electrode array by moving the cathode in bipolar stimulation.

Model Drop-down List
The model drop-down list is used to select the type of lead that is being used. The default selection is the Boston Scientific SC-2108-xx Linear lead.
Description

The Patient Options screen allows viewing and editing of additional program settings for a patient such as stimulation cycling, ramp up time, and maximum amplitude. Additionally, options to lockout rate and pulse width control in the Remote Control are provided. The selected options are downloaded to the Remote Control. Program settings are applied to all programs saved in the Remote Control/Stimulator.

Access/Exit

- To access “Patient Options,” select [Remote], then [Patient Options].
- To save parameters click [OK].

Immediately after clicking [OK] you must Save the current program to a slot on the Remote Control (see “Saving a Program on the Remote” in the “Remote Control” section below).

**WARNING:** Not Saving the current program or not performing one of the actions listed in footnote 1 immediately after clicking [OK] may result in the patient not feeling subsequent stimulation changes during the programming session, which may result in unintended over stimulation. For Patients using therapy that does not generate paresthesia (i.e., subperception therapy) it is less likely that unintended overstimulation will occur.

- To exit without saving click [Cancel].

Cycle

The Cycle selection determines the on and off duration of stimulation delivery.

- Check the “Cycle” box, and then set the On and Off duration.

Ramp Time

Ramp time is the amount of time to gradually increase stimulation from zero to the programmed amplitude.

- Check the “Ramp Up” box, then set the time of the ramp.

Max mA

Set Max mA to limit stimulation amplitude level. Max mA is applied to all programs saved in the Remote Control/Stimulator.

Lockout

The lockout selection provides or denies patient’s access to the Remote Control pulse width and rate control.

- Check/Uncheck the appropriate box to lockout/provide access to the pulse width and rate controls in Remote Control.

Battery, Program Use and Charge Profile

- Check [Battery Use], [Program Use] and or [Charge Profile], and click [Retrieve] to obtain the Battery Use (Implant only), Program Use and Charge Profile (if supported by Implant) information.

Additional Information

- Parameter settings apply to all Remote programs.
- Click System to access and modify default settings for new patients.

Program Database

Description

The Program Database screen provides a listing of all stimulation programs. Programs can be previewed and activated from this screen.

Access/Exit

- To access “Program Database,” select [Remote], then [Program Database].
- To exit, select [Remote] or [Back] to return to the “Remote Control” screen or [Finish] to return to the “Start Screen.”

Preview

Before overwriting the currently stimulating program with a program from the program database, program in the Program Database can be previewed. Click on [Preview]. The currently stimulating program will be stopped and the selected program will be activated temporarily until [End Preview] is clicked. When [End Preview] is clicked, the original program will be activated.

- Click the [desired program] from the Program Database, then select [Preview].

Use the arrows to sequentially scroll through all programs.

- Click, [End Preview] to return to the previous active program.

Activate

The activate button takes a selected program from the Program Database and initiates the stimulation, replacing the currently stimulating program.

- Select the [desired program] and click [Activate] or [Activate (Stim off)]

  [Activate (Stim off)] activates a program with stimulation turned off.

  To modify a program, go to [Manual], make adjustments, then save it on the Remote Control. Alternately, click on [Re-NAV] to make changes/modify a program using Navigator.

- To save the currently stimulating program, go to “Remote Screen”.

- If an activated program is not optimal or to increase/decrease stimulation, select Manual to change the program.

Delete

- Click on a [Program] slot.
- Select [Delete] to erase the program from the program database.

Additional Information

- Click [Manual] to view electrode configurations of an active program.
- Click [VAS] to document pain levels.

---

1 If desired, instead of (1) Saving the active program, you may (2) Activate a program, (3) Start a new Bionic Navigator 1.2 session, or (4) Use OR Mapping, but you must perform one of these 4 actions listed.
Remote Control

Description
The Remote Control screen displays programs stored on the patient’s Remote Control, which can be activated, previewed, or deleted. Programs can also be saved on to the Remote Control from this screen.

Access/Exit
• To access “Remote Control,” select [Remote] in the lower right-hand corner of any screen.
• To exit “Remote Control” and return to the “Start Screen,” click [Finish].
• To return to the previous screen select [Back].

Saving a Program on the Remote
The active (currently stimulating) program can be saved to one of four program slots on the Remote Control.
• Click the desired [Program slot], then [Save To]. The active program will be saved to the selected program slot. If the Remote Control has all four slots stored, select the program to be overwritten with the new program, then select [Save To].
[✓] indicates last activated or saved program.

Activating a Program from the Remote
The Activate button takes a selected program from the Remote Control and activates it (initiates the stimulation program), replacing the currently stimulating program.
• Select the desired [Program slot] and click [Activate] or [Activate (Stim off)]
  [Activate (Stim off)] activates a program with stimulation turned off.
• To modify the program:
  Go to [Manual], make adjustments, then save it on the Remote Control.
  or
  Click on [Re-NAV] to make changes/modify a program using Navigator and then save it on the Remote Control.

Preview
Before overwriting the currently stimulating program with a program from the Remote Control, a program in the Remote Control can be previewed. Click on [Preview]. The currently stimulating program will be stopped and the selected program will be activated temporarily until [End Preview] is clicked. When [End Preview] is clicked, the original program is activated. This feature can help in determining which Remote Control program to overwrite when all program slots are filled.
• Click the desired [Program slot] from the Remote Control then select [Preview].
• Click, [End Preview] to return to the previous active program.

Re-NAV
To modify the currently stimulating program, click on [Re-NAV].

• The areas that can be re-navigated (modifiable using the Navigator) are mapped as “Marks” in the Navigator. The Coverage Area screen is displayed with options to [Redo] the navigable areas.

Delete
• Click on a [Program slot].
• To erase the program from the Remote Control select [Delete].

Immediately after clicking [Delete] you must Activate a program (see the section on “Activating a Program from the Remote” above).2

WARNING: Not Activating a program or not performing one of the actions listed in footnote 2 immediately after clicking [Delete] may result in the patient not feeling subsequent stimulation changes during the programming session, which may result in unintended overstimulation. For Patients using therapy that does not generate paresthesia (i.e., subperception therapy) it is less likely that unintended overstimulation will occur.

Additional Information
• Click [Program Database] to preview or activate programs saved in the database.
• Click [Manual] to view or modify electrode configurations and parameters of an activated program.
• Click [Battery] to determine battery status.
• Click [Patient Options] to change stimulation delivery features.
• Click [VAS] to document pain levels.

Stimulation Power Button

Description
The Stimulation (Stim) Power button will stop and start stimulation. When started, stimulation will ramp up to the stored amplitude levels for the active program settings.

Operation
• Click the red [Stop] button in the lower left-hand corner of any screen to stop stimulation.
• Click the green [Turn on] button to resume stimulation.

2 If desired, instead of (1) Activating a program, you may (2) Save a program, (3) Start a new Bionic Navigator 1.2 session, or (4) Use OR Mapping, but you must perform one of these 4 actions listed.
Section 6  Reports

Description
The Report screen is used to create a patient or clinic report. By selecting various options for individual patients or groups, the user can create, view, print, export or close database information. Reports can be generated by type, and each report can be customized through sorting filters.

Access/Exit
• To access “Reports,” select [Reports] in the top right hand corner of any screen.
• To exit, select [Finish].

Print and Export
• Select a [Report Type].
  
  Patient Information
  Patient information, clinic information, hardware information, stimulation settings, profile information, battery usage, case history, and patient notes for various time intervals.

  Patient List
  Last visit, serial number, implant date and physician.

  Clinical Outcomes
  Implant, last visit, physician, diagnosis, percentages and means, implant duration, mean age, replacements, explants, revisions, and average VAS scores.

  Clinic Activity
  Last visit, physician and patient follow-ups. May include reprogrammings, trials, lead implants, total patients, average durations, and total durations.

  Generic Report
  Programs, threshold measurement, impedances, battery usage profile, program usage profile, patient history, lead configuration. Parameters include: patient drop-down list (select by patient name), from date, to date and a checkbox to list result in ascending/descending order.

• Click on [Qualifiers] to sort.
• Click [Create a Report] then, select print or export.

Note: When printing without a printer set-up, the report will be saved to a file. The Save As dialog box may be displayed behind the current open window and may not be immediately accessible. You can access the Save As dialog box through the taskbar button Or; you can press Alt+Tab to switch the focus to the dialog box.
Section 7 Testing

Impedance

Description
The Impedance button is used to verify electrical integrity. Lead impedance is measured and displayed for each of the IPG’s 16 electrode contacts. Impedances over 4500 Ω are considered to be resultant from open or unconnected wires, displayed with an X.

Access/Exit
- To access lead impedance, click [Ω] from the Hardware Configuration Summary, (Config), or OR Mapping.
- To exit, click [Measure] or [Close] to exit.

Additional Information
- Even though an X indicates higher than normal impedances, electrodes may still be included in stimulation configuration.
- All measured impedances are saved into the database.

OR Mapping

Description
The OR Mapping screen is used to assess lead position and evaluate paresthesia coverage during surgery. OR Mapping allows both Electronic Trolling and manual electrode selection. Electronic Trolling (E-Troll) is a quick way to sweep the electrode array by moving the cathode in bipolar stimulation.

Model Drop-down List
The model drop-down list is used to select the type of lead that is being used. The default selection is the Boston Scientific’s SC-2108-xx Linear lead.

Access/Exit
- To access “OR Mapping,” select [OR Mapping] in the lower left-hand corner of any screen.
- To exit, select [Finish].

E-Troll
E-Troll activation enables trolling using the up, down, left and right arrows to move the stimulation focus. Any electrode can be selected to initiate Trolling. Manual electrode polarity configuration is disabled when E-Troll is on.

- Press the [E-Troll] button on.
- [Adjust amplitude] to a comfortable level.
- Use the up, down, left and right trolling arrows to [direct stimulation].
- Click on any electrode to jump to a desired target on the lead arrays.
  Stimulation will stop, and amplitude should be increased to continue trolling.
- [Adjust the amplitude, rate and pulse width] by clicking the appropriate arrow.
  Amplitude may need to be periodically adjusted during trolling to account for fluctuations in intensity perception.
- Click, and or click and hold the amplitude up and down arrows to increment / decrement amplitude step size. Amplitude step size will vary depending on arrow selection. Double arrows adjust by 3 step increments/decrements. Single arrows adjust by single step increments/decrements.

Manual Electrode Selection
Manual electrode selection is enabled when E-Troll is off. Electrode configurations are selectable.

- Click [Electrodes] to assign polarity.
  Once for (+) anode
  Twice for (-) cathode
  Three times for (0) polarity
- [Adjust the amplitude, rate, and pulse width] by clicking the appropriate arrows.
- Selecting additional electrodes while stimulating causes stimulation to be turned off. Adjust amplitude to a comfortable level.

Additional Information
- Impedance measurements can be repeatedly taken by pressing the Ω button.
- An X on the impedance measurement screen indicates out of range electrode measurements or electrodes that are not connected. If the electrodes are reconnected or the impedance measurements fall within the acceptable range, repeating the impedance measurement will clear the X.
Appendix A: How to Enable Medtronic Lead Support

This Appendix contains the steps to add support for Medtronic leads so that they may be programmed using the Bionic Navigator 1.2 Software.

1. From the main screen, click on SYSTEM in the top menu:

2. On the SYSTEM screen that appears, click the Add Lead button:

3. In the LEAD INFORMATION screen shown below:
   a. Enter a lead key code in the LEAD KEY CODE box.
      NOTE: The lead key codes are listed on the following page. The key codes are case sensitive and the dashes are required.
   b. Click the OK button.
   c. Verify that a pop-up message says “Lead Update is Successful”.
      If you do not see this message, re-check the code and return to step 3a.
   d. Click OK to close the pop-up message.
   e. Click the Clear button.
   f. Repeat steps 3a through 3e for each lead key code below.

<table>
<thead>
<tr>
<th>MDT Lead Name</th>
<th>Lead Key Code (case sensitive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3487A Pisces Quad</td>
<td>81C1-006549-C421</td>
</tr>
<tr>
<td>3887 Pisces Quad Compact</td>
<td>F822-006649-CD3D</td>
</tr>
<tr>
<td>3888 Pisces Quad Plus</td>
<td>64F3-006749-EEE8</td>
</tr>
<tr>
<td>3587A Resume II</td>
<td>8165-006A49-3EF4</td>
</tr>
<tr>
<td>3986A Resume TL</td>
<td>A614-006849-5D25</td>
</tr>
<tr>
<td>3998 Specify 1</td>
<td>3807-006B49-6EC0</td>
</tr>
<tr>
<td>1 Also applies to 3890 Pisces Z Quad</td>
<td></td>
</tr>
<tr>
<td>2 Also applies to 3999 Specify</td>
<td></td>
</tr>
</tbody>
</table>

4. Once all lead key codes have been entered:
   a. Click the CLOSE button to exit the LEAD INFORMATION screen.
   b. Then click the OK button to exit the SYSTEM screen.

5. IMPORTANT: Complete the Clinician Programmer Update Form at the end of this Appendix and fax it to SCS Customer Service.
# CLINICIAN PROGRAMMER UPDATE FORM

I enabled Medtronic leads on the Clinician Programmers listed below.

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Serial Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP 1:</td>
<td></td>
</tr>
<tr>
<td>CP 2:</td>
<td></td>
</tr>
<tr>
<td>CP 3:</td>
<td></td>
</tr>
<tr>
<td>CP 4:</td>
<td></td>
</tr>
<tr>
<td>CP 5:</td>
<td></td>
</tr>
</tbody>
</table>

Name: ___________________________ Title: ___________________________

Signature: ___________________________ Date: ___________________________

**NOTE:** Fax this completed form to SCS Customer Service appropriate for your region.
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