



Precision Spectra™ Clinician Remote Control

Directions for Use

SC-5532-1 Remote Control Kit

Rx ONLY

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

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Product Model Numbers

SC-5532-1 Remote Control Kit

Refer to the *Indications for Use* for indications and related information.

Refer to the appropriate *Information for Prescribers* manual for contraindications, warnings, precautions, adverse events summary, Physician instructions, storage and handling, component disposal, and contact information for Boston Scientific. Refer to the *Labeling Symbols Addendum* for an explanation of Labeling Symbols.

Refer to the following Directions for Use (DFU) for device specific instructions not included in this manual: *Precision Spectra™ System Implantable Pulse Generator DFU, Clinician Trial Manual, Surgical Leads DFU, Percutaneous Leads DFU, Precision Spectra System Programming Manual, and Programming Wand DFU.*

Refer to the *Limited Warranty* for warranty information.

[USA] For FCC rules and for clinical studies supporting the clinical use of the neurostimulation system, refer to the *Information for Prescribers* manual.

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Description

The Precision Spectra™ Remote Control (RC) is a handheld device that allows you to communicate with and control the Precision Spectra stimulator.

Basic Operation

The RC communicates with the Stimulator through a radio frequency (RF) telemetry link from a distance of up to 91.4 cm (36 inches).

Unlocking the RC

The RC goes into idle (or sleep) mode when not in use. It can be reactivated by pressing the Lock/Unlock button on the right side of the RC.

Turning Stimulation On/Off

Press the Stimulation ON/OFF button at any time to turn the Stimulator on or off.

Selecting Your Language/Screen Preference

The RC allows you to choose English text screens or Iconic screens. Refer to “Languages” on page 15 for additional instructions.

Note: Throughout this manual the English text screen is shown paired with the corresponding Iconic screen.

Adjusting Stimulation Amplitude on the Home Screen

The Home screen displays the number and name of the current Program, as well as information about the stimulation amplitude (Level) currently selected. The stimulation amplitude is displayed as both a graph and as a percentage of the maximum available limit.

1. Press the Home button on the left side of the RC to view the Home screen.



2. Press the Minus (-) button to decrease the level of stimulation.
3. Press the Plus (+) button to increase the level of stimulation.

Program Selection and Activation

1. Press the P button the left-hand side of the RC to display the Programs screen.

Note: You can also navigate to the Programs menu from the Main Menu. Refer to Accessing the Main Menu for additional instructions.



2. Select Change Program.

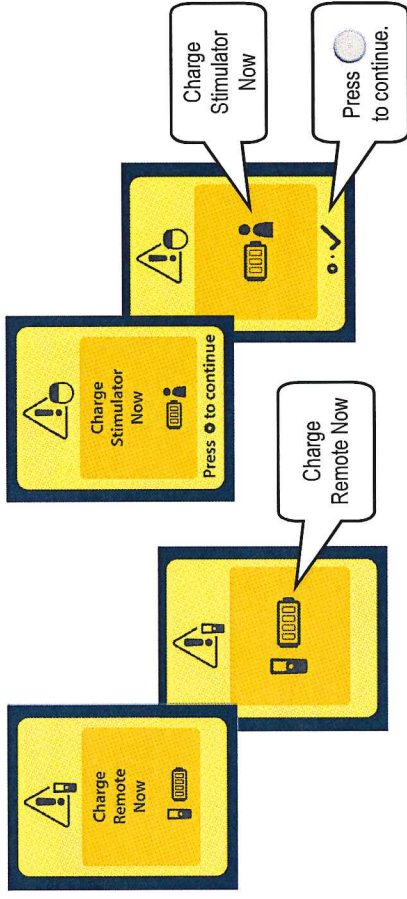


3. Press the Up and Down Arrow buttons to navigate to the desired Program.
4. Press the Right Arrow button to Select the Program.

Stimulator and RC Battery Status

The P icon at the top left of the Home screen indicates the charge level of the RC battery. The RC icon at the top right of the Home screen indicates the charge level of the Stimulator battery (right).

The RC will display messages reminding you to recharge the RC or the Stimulator if the battery power is low.



Recharging the RC

Recharge the RC battery by connecting the RC to the USB-Power Supply provided with the RC.



Accessing Additional Options from the Main Menu

The Main Menu gives you access to the following options:

- **P Programs** - Allows you to change to another program, save programs after modifications have been made, restore programs to clinical settings, and delete programs.
- **Stimulation Areas**
- **System Settings**

Accessing the Main Menu


1. Press the  button on the left-hand side of the RC to display the Home screen:
2. From the Home screen, press the Right Arrow  button to select the **Main Menu**.



Selecting Stimulation Areas to Modify Programs

Each Program can include settings for up to 4 Stimulation Areas. Each Stimulation Area is identified by a letter and a name. These Stimulation Areas control Amplitude, Pulse, Width, and Rate.

From the  Main Menu:

1. Select  **Stimulation Areas**. The Stimulation Areas screen displays.



2. Select the desired area. The Area screen displays with the following parameters options:




3. Select the parameter that you would like to modify.

Amplitude

From the Area screen:

1. Select  Amplitude.



2. Press the Minus  button to decrease the **Amplitude** (level) of stimulation.
3. Press the Plus  button to increase the **Amplitude** (level) of stimulation.

Pulse Width

From the Area screen:

1. Select **Pulse Width**.

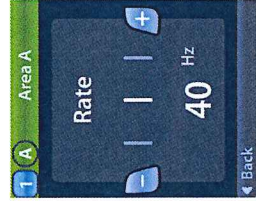


2. Press the Minus **-** button to decrease the **Pulse Width**.
3. Press the Plus **+** button to increase the **Pulse Width**.

Rate

From the Area screen:

1. Select **Rate**.



2. Press the Minus **-** button to decrease the **Rate**.
3. Press the Plus **+** button to increase the **Rate**.

Saving Modified Programs

If the stimulation amplitude, pulse width, or rate have been changed, the new settings can be saved as the default stimulation for that Program. The new settings will remain until a new change is saved or the Program is restored to its Clinic Settings. Refer to Restoring Programs for additional information.

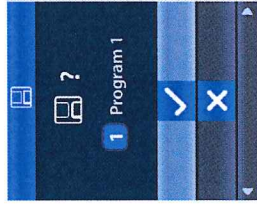
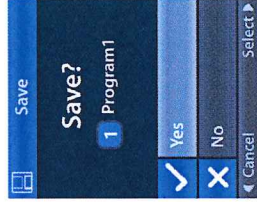
1. Press the **P** button the left-hand side of the RC.

or

From the **Main Menu** screen, select **P Programs**



2. Select **Save**. The **Save ?** screen displays.



3. Select **Yes - Save**

or

Select **No - Discard**.

Restoring Programs

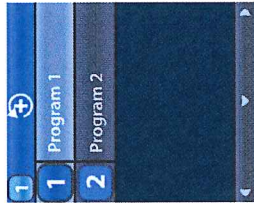
If after saving changes to a Program, you decide that you want to revert the Program back its Clinic Settings, you can do so by restoring the Program.

1. Press the **P** button the left-hand side of the RC.

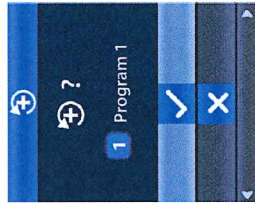
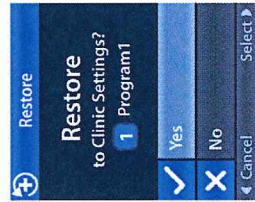
or

From the **Main Menu** screen, select **P Programs**.

2. Select **Restore to Clinic Settings**. The Restore screen displays.



3. Select the Program you want to restore. The Restore confirmation screen displays.



4. Select **Yes** to restore the Program to the Clinic Settings.

or

Select **No** to cancel the action.

Copying Programs:

You can copy an existing program to a new program.

1. Press the **P** button the left-hand side of the RC.

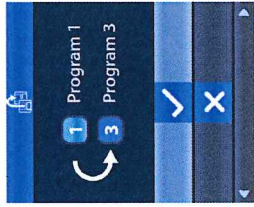
or

From the **Main Menu** screen, select **P Programs**.

2. Select **Copy to...**



3. Select the Program that you want to copy the current Program to.
4. The **Overwrite?** screen displays if you are not copying to an empty slot.



5. Select **Yes** to Overwrite the Program.

or

Select **No** to cancel the action.

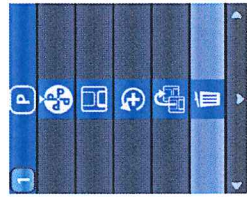
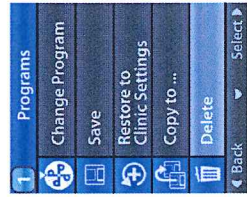
The Copy to.... confirmation screen displays.

Deleting Programs

1. Press the **P** button the left-hand side of the RC.

or

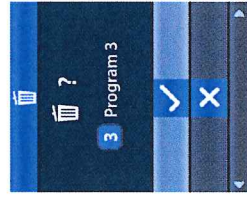
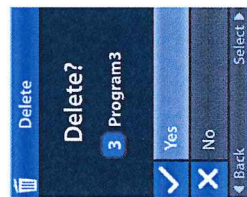
- From the **Main Menu** screen, select **Programs**.



2. Select **Delete**.



3. Select the program to delete.



4. Select **Yes** to Delete the selected program.

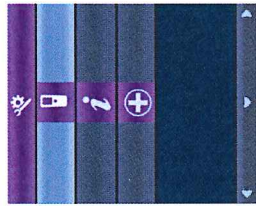
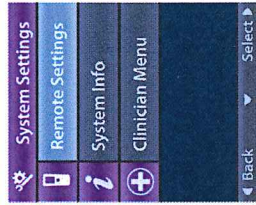
or

- Select **No** to cancel the action.

Accessing System Settings

From the **Main Menu**:

1. Select **System Settings**. The System Settings screen displays.



Remote Settings

The Remote Settings option allows you to adjust the Alert Volume, Screen Brightness, and to select your language preference.

From the System Settings menu:

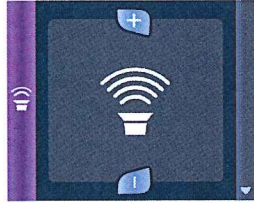
1. Select **Remote Settings** to display the Remote Settings menu.



Alert Volume

From the Remote Settings menu:

1. Select **Alert Volume**.

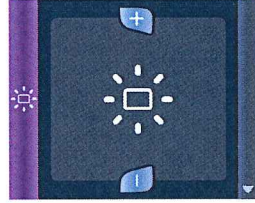
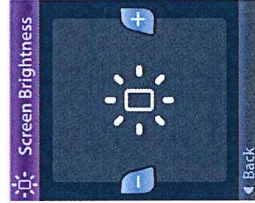


2. Press the Minus (-) button to decrease the **Alert Volume**
3. Press the Plus (+) button to increase the **Alert Volume**.

Screen Brightness

From the Remote Settings menu:

1. Select **Screen Brightness**.



2. Press the Minus (-) button to decrease the brightness
3. Press the Plus (+) button to increase the brightness.

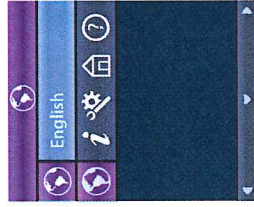
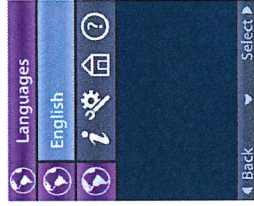
Languages

The RC allows you to configure your system to display one the following:

- English language text screens
- Iconic screens

From the Remote Settings menu:

1. Select **Languages**.




2. Select the **English** or **iconic display**.

The Languages confirmation screen displays to confirm your selection.



System Info


The System Info menu gives you the option of viewing information regarding the RC or the Stimulator.

From the  System Settings menu:

1. Select  System Info.



Remote Info

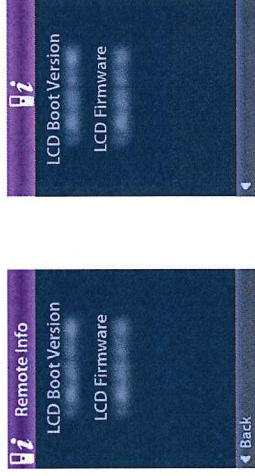
1. Select  Remote Info to view the Remote Info screen.



The Remote Info screen displays the following information:

- Serial Number
- Model Number
- Boot Version
- Firmware Version

2. Select More to view additional Remote Info.



The Remote Info screen displays the following additional information:

- LCD Boot Version
- LCD Firmware

Stimulator Info

1. Select  Stimulator Info to view the Stimulator Info screen..




The Stimulator Info screen displays the following information:



- Serial Number
- Model Number
- Boot Version
- Firmware Version

Note: The Model number and Serial number for the Trial Stimulator can be found by removing the battery compartment cover on the Trial Stimulator.


Accessing the Clinician Menu

The Clinician menu allows you to link to a Stimulator, clear the link to a Stimulator, check impedances, and reset the Stimulator. It also allows you to use the Remote Control without any of the lockouts that may have been programmed by the Clinician Programmer (e.g., Main Menu, Programs, Pulse Width, Rate). To enter the Clinician Menu you must enter a password.

From the  System Settings menu:

1. Select the  Password screen. The  Password screen displays.

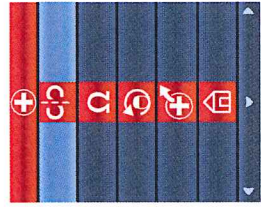


2. Use the Navigation  buttons to Enter your password.

Or

Use the Navigation  buttons to Cancel.

If the password is incorrect, the  Invalid Password screen displays. If the password is correct, the Clinician Menu displays.




Note: If the remote is not linked to a Stimulator, the Stimulator Search option displays on the Clinician Menu instead of the Clear Link option.


Stimulator Search

The Clinician Menu allows you to search for a stimulator and link to it.

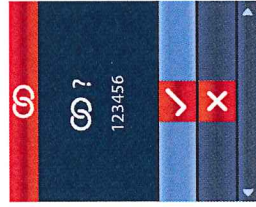
From the Clinician Menu:


1. Select  Stimulator Search. The Stimulator Search screen displays.




2. If the desired Stimulator has not been located, select  Rescan.

3. Select the Stimulator that you wish to link to. The  Link to Stimulator #####? screen displays.



4. Select  Yes to link to the Stimulator.

or

- Select  No to cancel the action.

Clear Link

If the RC is linked to a Stimulator, the **Clear Link** option displays on the Clinician Menu.



From the Clinician Menu:

1. Select **Clear Link**. The **Clear Link to Stimulator?** screen displays.



2. Select **Yes** to clear the link to the Stimulator.

or

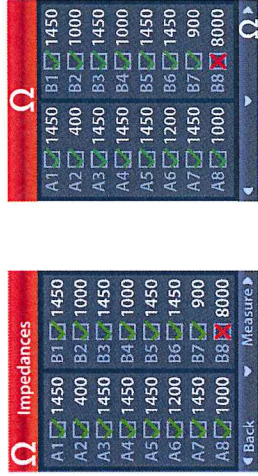
Select **No** to cancel the action.

Impedances

You can use the RC to check impedances.

From the Clinician Menu:

1. Select **Impedances**. The Impedances screen displays.



2. Select **Measure** to check impedances.

3. Select **Back** to go back to the Clinician Menu.

Reset Stimulator

You can use the RC to reset the Stimulator.

From the Clinician Menu:

1. Select **Reset Stimulator**. The **Reset Stimulator?** screen displays.



2. Select **Yes** to reset the Stimulator.

or

Select **No** to cancel the action.

Exit Clinician Mode

From the Clinician Menu:

1. Select **Exit Clinician Mode**. The System Settings screen displays.

Troubleshooting

Telemetry Help

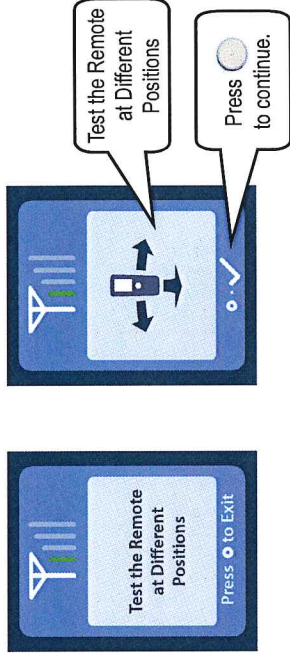
The RC has an effective communication range of up to 91.4 cm (36 inches) with the Stimulator. Common sources of interference, such as televisions and computer monitors, can affect wireless communication. If the RC is unable to communicate with the Stimulator, the Telemetry Error message will appear:



To retry communication with the Stimulator – this resends the last command – select **Retry** . To cancel communication and return to the screen, press .

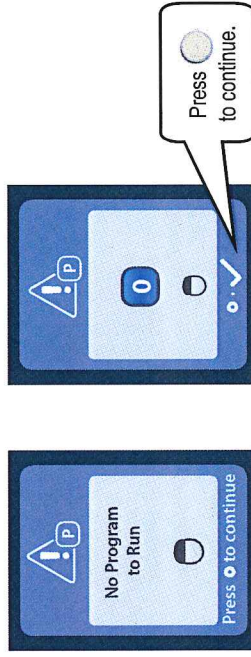
The Telemetry Help tool is also available to assist you in improving communication between the RC and the Stimulator. To use the Telemetry Help tool, select **Telemetry Help** . The following screen will be displayed:

The telemetry bars indicate the strength of wireless communication. The number of bars will change depending on the distance and orientation of the RC from the Stimulator. This tool will continue to measure the strength of communication for 30 seconds or until is pressed.



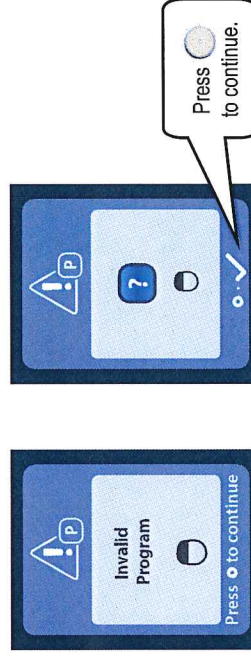
No Program to Run Screen

This screen is displayed when the Stimulator has no Programs to run.



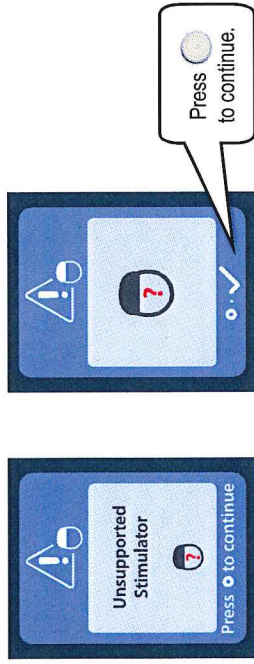
Invalid Program Screen

This screen is displayed when the Stimulator attempts to run an invalid Program.



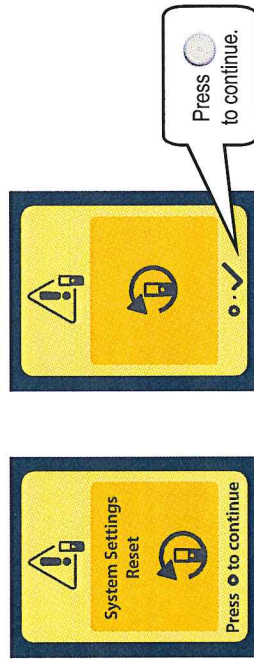
Unsupported Stimulator Screen

This screen is displayed when the RC detects an incompatible Stimulator.



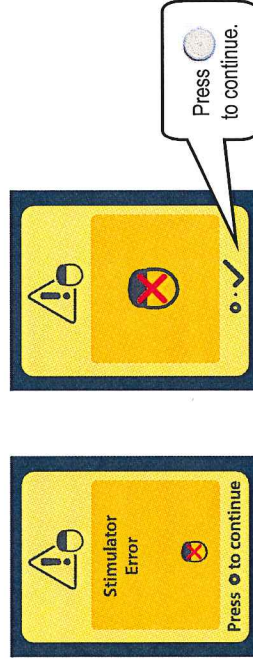
System Settings Reset Screen

This screen is displayed when the RC experiences an error and a reset of the RC is required. Press [button] to continue. All RC settings will be restored to the default factory settings.



Stimulator Error Screen

This screen is displayed when there is a non-critical Stimulator error. Press [button] to acknowledge the message and continue.



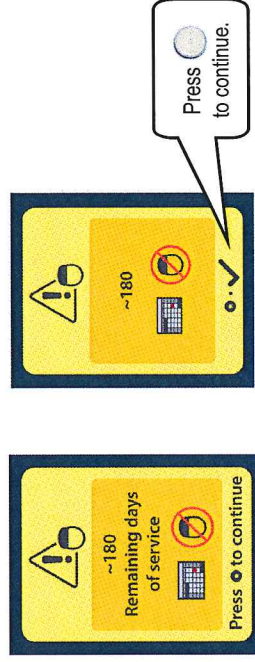
Remote Error Screen

This screen is displayed when there is a critical error on the RC which causes the RC to be unusable. Please contact Boston Scientific or your healthcare provider to order a replacement RC.



End of Programmed Service




















The Stimulator software has been programmed to end service after a defined period. When the Stimulator is within approximately 180 days of the end of its programmed period, the RC will display the following on-screen message.















Press [button] to clear the message. The message will reappear approximately weekly until the end of the Stimulator's programmed period is reached. When the end of its programmed period is reached, the RC will display the following on-screen message.



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	A	Alert Volume 13, 14		N	Navigation 18
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