Freelink™ Remote Control

Directions for Use

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.
Guarantees
Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.
Drawings are for illustration purposes only.

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Additional Information
For Indications and related information, see the Indications DFU. For contraindications, warnings, precautions, adverse events summary, physician instructions, storage and handling, component disposal, and contact information for Boston Scientific, refer to the Information for Prescribers DFU for your spinal cord stimulator system. For other device-specific information not included in this manual, labeling symbols, and warranty information, refer to the appropriate DFU for your SCS System as listed on your Reference Guide.

Product Model Numbers

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<td>Freelink™ Remote Control</td>
</tr>
<tr>
<td>SC-5261*</td>
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*With integrated Bluetooth® Low Energy technology.
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Description

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

Caution

• Keep the RC dry. It should not be exposed to moisture.
• Do not connect the RC USB port to any other device except to the RC charger provided with it.
• Keep the RC away from pets, pests and children to avoid damage to the device.

Remote Control Features

1. **Screen**: displays all menus, icons, and messages
2. **Lock/Unlock Button** 🕰️: unlocks the Remote Control from sleep mode.
3. **Programs Button** 📋: displays the Programs menu.
4. **Home Button** 🏘️: displays the Home screen.
5. **Therapy Button** 🌟: Turns Therapy ON or OFF
6. **Minus Button** —: Decreases selected parameter
7. **Plus Button** +: Increases selected parameter
8. **Navigation Buttons** ⬇️ and ⬆️: allows scrolling through a selected menu
9. **Navigation Buttons** ⬅️ and ➤️: makes a selection
10. **Navigation Button** ◀️: returns to the previous screen
11. **USB Port** (not shown): allows recharging of the Remote Control with the USB power supply.
Basic Operation

The RC communicates with the Stimulator through a radiofrequency (RF) telemetry link. The RC has an effective communication range of up to 91.4 cm (36 inches) with the Boston Scientific rechargeable Stimulator, and a nominal effective communication range of 55.9 cm (22 inches) with the Boston Scientific non-rechargeable Stimulators.

As an operator of this device, perform only the following service and maintenance tasks on the device:

• Recharging, see “Recharging the RC” on page 27
• Cleaning

Ensure that this device is not in use while performing service and maintenance tasks.

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 Therapy On/Off

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

Selecting Your Language/Screen Preference

The RC allows you to choose either an iconic screen or a text screen in one of the languages provided. Refer to “Languages” on page 18 for additional instructions.

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

Note: All features of the RC listed in this manual may not be available to you (for example, Schedules and Bluetooth Settings). The settings displayed are dependent on the RC, stimulator, and therapy configurations.
The Home Screen

The Remote Control (RC) Home screen displays information for the specific stimulator and stimulation therapy programmed. If a program is running, the Home Screen will display the following information:

- Name of the Program
- Number of the Program
- Stimulation Amplitude (Level) selected, as both a graph and a percentage of the maximum available limit

**Example: Home Screens for Stimulators with Active Program**

![Home Screen Example](image1)

**Note:** When the RC connects to a non-rechargeable Stimulator, the RC will not display the Stimulator battery icon in the upper right corner of the Home screen.

If a Schedule is running, the Home Screen will display the following information about the Schedule and the Programs within the Schedule:

- Number of the Schedule
- Name of the Schedule
- Number of the active Program within the Schedule
- Name of the active Program within the Schedule
- Total Time that the active Program will run
- Time that elapsed for the active Program

**Example: Home Screens for Stimulators with Active Schedules**

![Home Screen Example](image2)

**Note:** The Schedules feature is available only when connected to the Spectra WaveWriter™ Stimulator.
Adjusting Stimulation Amplitude from the Home Screen

1. Press the Home button on the left side of the RC to view the Home screen.
   
   **Note:** When the RC connects to a non-rechargeable Stimulator, the RC will not display the Stimulator battery icon in the upper right corner of 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.

The Main Menu

The **Main Menu** provides access to the following options:

- Programs
- Schedules
- Therapy Rating
- Stimulation Areas
- System Settings

Accessing the Main Menu

**Note:** Depending on stimulator configurations, some selection may be unavailable.

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

2. From the Home screen, press the Right Arrow button to select the Main Menu.
Program Selection and Activation

The Programs Menu allows patients to change to another program, save modifications to Programs, restore programs to clinic settings, and delete programs.

1. Press the P button on the left 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 by pressing the Selection button or pressing the Right Arrow button.

3. Press the Up or Down Arrow buttons to navigate to the desired Program.

4. Press the Right Arrow button to Select the Program.
**Selecting Stimulation Areas to Modify Programs**

Each Program can include settings for up to four 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.

   ![Stimulation Areas Screen](image1)

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

   ![Area Screen](image2)

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

**Amplitude**

From the Area screen:

1. Select Amplitude.

   ![Amplitude Screen](image3)
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 side of the RC.
   
   or

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

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

3. Select **Yes** to save.
   
   or

   Select **No** to discard.
**Restoring Programs**

Restoring Programs removes saved changes to a Program and resets the Program to the original Clinic Settings.

1. Press the \( P \) button on the left side of the RC.
   
   or
   
   From the \( \equiv \) Main Menu screen, select \( P \) Programs.

2. Select \( \oplus \) Restore to Clinic Settings. The Restore screen displays.

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

4. Select \( \checkmark \) Yes to restore the Program to the Clinic Settings.
   
   or
   
   Select \( \times \) No to cancel the action.
Copying Programs
You can copy an existing Program to a new Program.

1. Press the P button on the left side of the RC.
   or
   From the ã Main Menu screen, select P Programs.
2. Select P 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 \textbf{P} button on the left side of the RC.

or

From the \textbf{Main Menu} screen, select \textbf{Programs}.

2. Select \textbf{Delete}.

3. Select the Program to delete.

4. Select \textbf{Yes} to Delete the selected program.

or

Select \textbf{No} to cancel the action.
Managing Schedules

Schedules allows patients to select and change to a different schedule, exclude programs from a schedule, or advance to the next program in a schedule.

Note: Depending on the stimulator configurations, some selections may be unavailable.

From the Main Menu:

1. Press the Down Arrow to navigate to Schedules.

2. Once Schedules is highlighted, press the Selection button or the Right Arrow button to access the Schedules Menu screen.

Selecting or Changing to a Different Schedule

From the Schedules Menu:

1. Select Change Schedule by pressing the Selection button or the Right Arrow button.
2. Press the Up ⬆️ or Down ⬇️ Arrow buttons to navigate to the desired Schedule.
3. Press the Right Arrow ↘️ button to Select the Schedule.

**Exclude Program from a Schedule**

From the **Schedules Main Menu**:

1. Press the Down Arrow ⬇️ button to navigate to Exclude Program.

2. Select Exclude Program by pressing the Right Arrow ↘️

3. Press the Up ⬆️ or Down ⬇️ Arrow buttons to select Yes or No at the prompt.
4. If Yes is selected, the Program Excluded screen displays.
5. If No is selected, the program will not be excluded and you will be redirected to the Schedules Menu:

**Advance Program within a Schedule**

From the Schedules Menu:

1. Press the Down Arrow button to navigate to Next Program.

2. Select Next Program by pressing the Right Arrow.

3. Press the Up or Down Arrow buttons to select Yes or No at the prompt.
4. If Yes is selected, the Program Advanced screen displays:

5. If No is selected, the program will not be advanced and you will be redirected to the Schedules Menu:
**Entering a Therapy Rating**

The Therapy Rating is a way for the patient to communicate real time preferences to different therapy types. Their preferences are recorded on a five star rating scale.

**Note:** Depending on stimulator configurations, some selections may be unavailable.

From the Main Menu:

1. Press the Down Arrow to navigate to Therapy Rating.

2. Once Therapy Rating is highlighted, press the Selection button or the Right Arrow to access the Therapy Rating screen.

3. Press the Up or Down Arrow buttons to navigate to the rating of the therapy at that moment.

4. Press the Right Arrow button to make a selection.
**Accessing System Settings**

From the **Main Menu**:

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

   ![System Settings Screen](image)

When using the Precision Montage MRI Stimulator, the Lead Check icon will also appear on the System Settings screen:

![System Settings Screen with Lead Check](image)

**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.
   
   ![Alert Volume Interface]

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.
   
   ![Screen Brightness Interface]

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 of the following:
- Text screen in one of the languages provided
- Iconic screen

From the Remote Settings menu:
1. Select Languages.
2. Select the desired language, such as 🇺🇸 English or 🇮🇹 iconic display. The Languages confirmation screen displays to confirm your selection.

**Pass-Through Mode**

Pass-Through Mode allows the stimulator to send information to a compatible mobile device. The mobile device must have both the Boston Scientific Application installed and Bluetooth wireless technology to be compatible. The Boston Scientific Application controls Pass-Through Mode. Pass-Through Mode can start after successfully pairing the RC to a compatible mobile device.

**Pausing Pass-Through Mode Using the RC**

Keeping the RC locked temporarily stops the Bluetooth wireless connection. The Bluetooth wireless connection will resume after unlocking the RC if the Boston Scientific application on the compatible mobile device is still connected to the RC.

The Bluetooth wireless connection will not resume after unlocking the RC if the Boston Scientific application on the compatible mobile device is disconnected from the RC.

From **Pass-Through Mode**:

1. Press the Selection 🔄 button.
2. The Lock screen displays to confirm Pass-Through Mode has stopped.
**Bluetooth Settings**

Bluetooth Settings allows you to Pair New Device and Clear All Pairings.

From the **System Settings** menu:

1. Select Bluetooth Settings to display the Bluetooth Settings menu.

   ![Bluetooth Settings Menu]

**Pair New Device**

From the **Bluetooth Settings** menu:

2. Enter the Pairing Passcode in the compatible mobile device.
3. The Pairing Successful confirmation screen displays on the RC to confirm device pairing.

**Clear All Pairings**

Clearing device pairings stops the Bluetooth wireless connection. The Bluetooth wireless connection will resume after you Pair a Device.

From the **Bluetooth Settings** menu:

1. Select Clear All Pairings.
2. Select Yes to confirm. 
   
   or
   
   Select No to cancel.
Note: You can also access the Clear All Pairings Screen from the Lock screen, by pressing (and holding) the minus button.

**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

2. 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
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](image)

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 Clinician Menu. 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:


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 Ω 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:


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.
**Lead Check (Precision Montage MRI Stimulator Only)**

For the Precision Montage MRI Stimulator, you can use the Remote Control to test lead integrity. From the Systems Settings menu:

1. Select 📡 Lead Check

![Impedances](image)

**Recharging the RC**

The 🌡️ icon at the top left of the Home screen indicates the charge level of the RC battery. The RC will display messages reminding you to recharge the RC or the Stimulator if the battery power is low.

![Charge Remote Now](image)
Recharging the RC

Recharge the RC battery by connecting the RC to the USB-Power Supply provided with the RC. The RC battery has a typical service life of 400 charging cycles.

External Trial Stimulator or Rechargeable Stimulator Only

Note: The following is not applicable to the Precision Novi Stimulator.

The icon at the top right of the Home screen indicates the charge level of the Stimulator battery. The RC will display messages reminding you to recharge the Stimulator if the battery power is low.
Troubleshooting

Telemetry Help
The RC has an effective communication range of up to 91.4 cm (36 inches) with the Boston Scientific rechargeable Stimulator, and a nominal effective communication range of 55.9 cm (22 inches) with the Boston Scientific non-rechargeable Stimulator. Common sources of interference, such as televisions and computer monitors, can affect wireless communication. You will continue to have access to the RC menus even if the RC is outside its effective communication range. If you enter a command to change your settings or programs while the remote control is outside of its effective communication range, you will have several seconds to move the RC within range of the Stimulator to send the command. After the command is received by the Stimulator, the remote control will make a double-beep then display the requested change on the screen. 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:
Troubleshooting

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 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 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. Advise the patient to contact Boston Scientific or their 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 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.
Non-rechargeable IPG Battery Status

**ERI (Elective Replacement Indicator) Screen**
The implanted non-rechargeable Stimulator is nearing end of service. Changes made to the stimulation will not be saved, and stimulation will not be available soon. Advise the patient to contact their healthcare provider to report this message. Press the select key to clear this information screen. This screen will appear whenever the RC is activated.

![Stimulator near end of service. Call your doctor.](image1)

**End of Battery Life Screen**
The implanted non-rechargeable Stimulator has reached its end of service. Stimulation is not available. Advise the patient to call their healthcare provider.

![Stimulator at end of service. Call your doctor.](image2)
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