Freelink™ Remote Control

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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.

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

Cautions
• 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.

Basic Operation
The RC communicates with the Stimulator through a radio frequency (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.

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 either an iconic screen or a text screen in one of the languages provided. 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.

Home Screens with Rechargeable Stimulator

Home Screens with Non-rechargeable Stimulator
**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.

**Program Selection and Activation**

1. Press the 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.

3. Press the Up or Down Arrow buttons to navigate to the desired Program.
4. Press the Right Arrow button to Select the Program.
**RC Battery Status**

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.

![Remote Control Battery Service Life](image)

**Remote Control Battery Service Life**

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.

![Charge Stimulator Now](image)

Press ⬇️ to continue.

![ETS Battery Low](image)

Press ⬇️ to continue.
Accessing Additional Options from the Main Menu

The Main Menu gives you access to the following options:

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

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

**Amplitude**

From the Area screen:

1. Select \[\text{Amplitude}\].

2. Press the Minus \[\text{button}\] to decrease the Amplitude (level) of stimulation.

3. Press the Plus \[\text{button}\] 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.
Accessing Additional Options from the Main Menu

**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 \( \textbf{P} \) button the left side of the RC.

   or

   From the \( \equiv \) Main Menu screen, select \( \textbf{P} \) Programs

2. Select \( \equiv \) Save. The Save ? screen displays.

3. Select \( \checkmark \) Yes to save.

   or

   Select \( \times \) No to 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 on the left side of the RC.
   or
   From the Main Menu screen, select 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 on the left side of the RC.
   or
   From the Main Menu screen, select 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 on the left 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:


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

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 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.

**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 \[i\] 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 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 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.

![Clinician Menu](image1)

**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.

![Stimulator Search](image2)

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 Ω 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:
1. Select \( \Rightarrow \) Reset Stimulator. The Reset Stimulator? screen displays.

   ![Reset Stimulator Screen](image)

   ![Reset Stimulator Screen](image)

2. Select \( \checkmark \) Yes to reset the Stimulator.
   or
   Select \( \times \) No to cancel the action.

**Exit Clinician Mode**

From the Clinician Menu:

1. Select \( \Rightarrow \) 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 \( \Rightarrow \) Lead Check

   ![Impedance Screen](image)
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:
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 \( \text{ } \) 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.

![Unsupported Stimulator Screen](image1)

Press to continue.

**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.

![System Settings Reset Screen](image2)

Press to continue.

**Stimulator Error Screen**

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

![Stimulator Error Screen](image3)

Press to 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.

![Remote Error Screen](image)

**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.

![End of Programmed Service](image)

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.

![End of Programmed Service](image)
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. Contact your clinician to report this message screen. Press the select key to clear this information screen. This screen will appear whenever the RC is activated.

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**End of Battery Life Screen**

The implanted non-rechargeable Stimulator has reached its end of service. Stimulation is not available. Call your clinician.
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