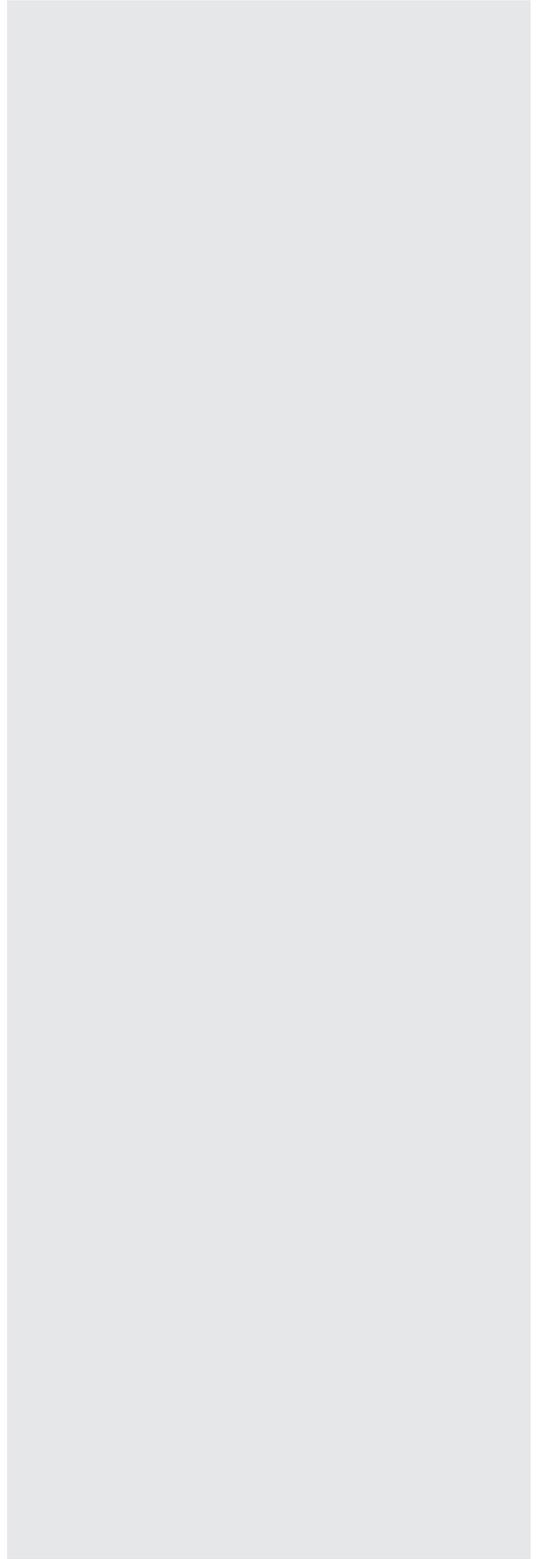


Vercise™ DBS
Remote Control 3
Directions for Use



Vercise™ DBS Remote Control 3 Directions for Use

Trademarks

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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.

Additional Information

For indications, contraindications, warnings, precautions, adverse events summary, sterilization, component disposal, and storage and handling, refer to the *Information for Prescribers DFU*. For other device-specific information not included in this manual or labeling symbols, refer to the appropriate DFU as listed on your *DBS Reference Guide*.

Technical Support

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

Product Model Numbers

Model Number	Description
DB-5552-1	Vercise DBS Remote Control 3 Kit
DB-5250-S	Vercise DBS Remote Control 3
NM-6210	Remote Control Holster
NM-6315	USB Power Supply, Remote Control, Universal
NM-6310	USB Power Supply, Remote Control, North America

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Description

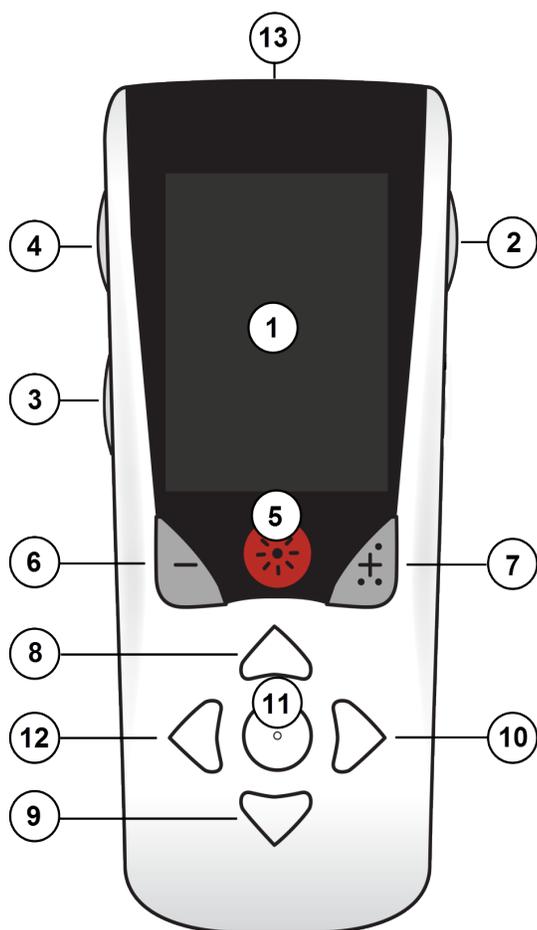
The Remote Control is a hand-held device that communicates with the Stimulator through a radio frequency (RF) telemetry link. The Remote Control functions include the following:

- Linking/De-Linking to a Stimulator
- Turning stimulation ON and OFF
- Increasing stimulation amplitude
- Changing and restoring Programs
- Accessing Clinician Menu Options
- Customizing Remote Control settings: language, volume, brightness
- Enabling/Disabling MRI Mode for MR conditional Vercise Gevia Stimulator

Cautions

- Keep the Remote Control dry. It should not be exposed to moisture.
- Do not connect the Remote Control USB port to any other device except to the Remote Control charger provided with it.
- Keep the Remote Control 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** **P**: displays the Programs menu.
4. **Home Button** : displays the Home screen.
5. **Stimulation Button** : Turns stimulation ON or OFF.
6. **Minus Button** : Decreases selected parameter.
7. **Plus Button** : Increases selected parameter.
- 8, 9. **Navigation Buttons**  and : allow scrolling through a selected menu.
- 10, 11. **Navigation Buttons**  and : make a selection.
12. **Navigation Button** : returns to the previous screen.
13. **USB Port (not shown)**: allows recharging of the Remote Control with the USB power supply.

The Remote Control has an average communication range of 22 inches (55.9 cm) with the non-rechargeable Vercise™ PC Stimulator and an average communication range of 36 inches (91.4cm) with the rechargeable Vercise Gevia™ Stimulator. When using the Remote Control, avoid common sources of interference, such as televisions and computer monitors. For additional telemetry information, see the *Telemetry Help* section.

Basic Operation

Unlocking the Remote control

The Remote Control 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 Remote Control.

Turning Stimulation ON/OFF

After unlocking the Remote Control, press the Stimulation ON/OFF  button to turn the Stimulator ON or OFF.

Selecting Your Language/Screen Preference

The Remote Control allows you to choose either an iconic screen or a text screen in one of the languages provided. See the *Languages* section for additional instructions.

Note: *Throughout this manual, both the English text and the iconic screens are shown.*

The Home Screen

After unlocking the Remote Control, the Home screen  will appear if the Remote Control was previously linked to a Stimulator. The Home screen shows the number of the active program, stimulation status (ON/OFF), navigation to the Main Menu, and the Stimulator battery level for Rechargeable Stimulators. It also shows the battery level of the Remote Control (see *Remote Control Battery* section). The Home screen can be accessed from any other screen by pressing the Home  button.

1. Press the **Home**  button on the left side of the Remote Control to view the Home screen.

Home Screen for Rechargeable Stimulator



Note: *When the Remote Control connects to a rechargeable Stimulator, it will display the current battery level of the Stimulator on the Home screen.*

Home Screen for Non-Rechargeable Stimulator



Note: When the Remote Control connects to a non-rechargeable Stimulator, the battery level of the Stimulator will not be displayed on the screen.

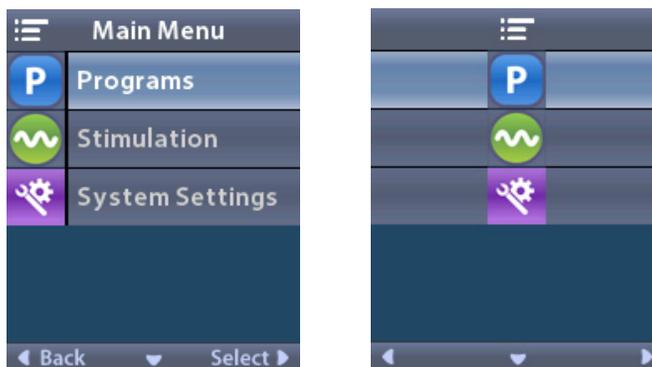
Accessing Additional Options from the Main Menu

The **Main Menu** gives you access to the following options:

- Programs
- Stimulation
- System Settings

Accessing the Main Menu

1. Press the button on the left side of the Remote Control to display the Home screen.
2. From the Home screen, press the right arrow button to select the **Main Menu**.



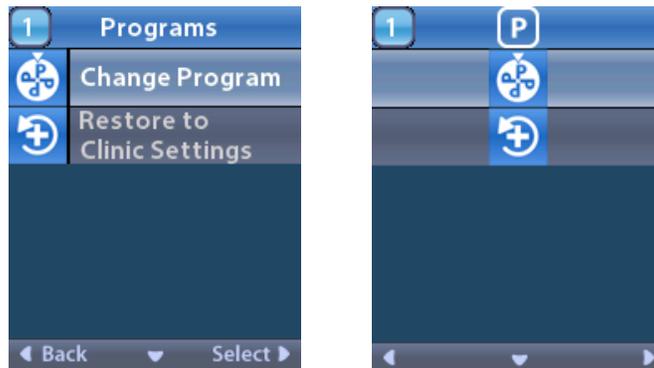
Note: When the Stimulator has no programs saved on it, the Main Menu will only display the System Settings option.

Program Selection and Activation

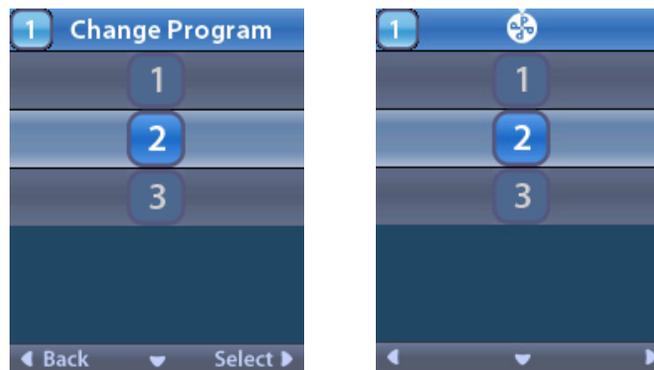
A stimulation program is a set of stimulation parameters that determine the patient's therapy. A program may apply stimulation to as many as four independent stimulation fields or areas, depending on how the program is set up. For example, one area may correspond to a right brain target, while another area may correspond to a left brain target. The Remote Control can store up to four programs – numbered 1 through 4 – for the patient to select and activate at any time.

1. Press the **P** button on the left side of the Remote Control to display the Programs screen.

Note: You can also navigate to the Programs menu from the Main Menu. Refer to the *Accessing the Main Menu* section 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.

Restoring Programs

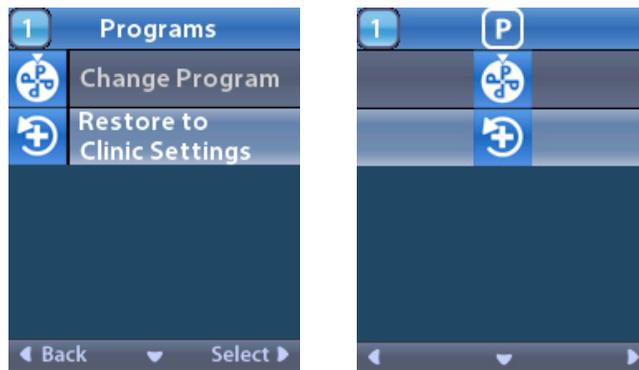
If after changing a program, you decide that you want to revert the program back to its clinic settings, you can do so by restoring the program.

1. Press the **P** button on the left side of the Remote Control.

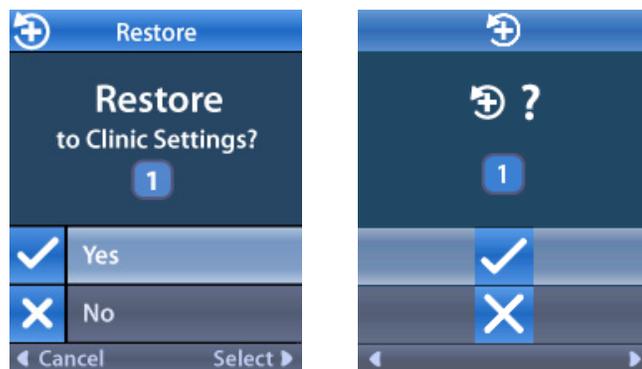
or

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

Select  **Restore to Clinic Settings**. The Restore screen displays a list of programs to restore.



2. Select the program you want to restore. The Restore Confirmation screen displays.



3. Select  **Yes** to restore the program to the clinic settings.

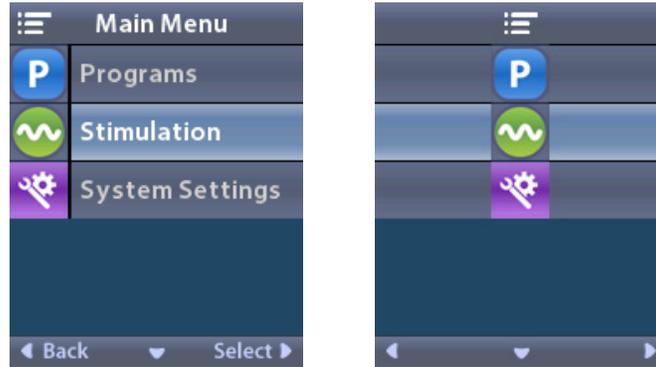
or

Select  **No** to cancel the action.

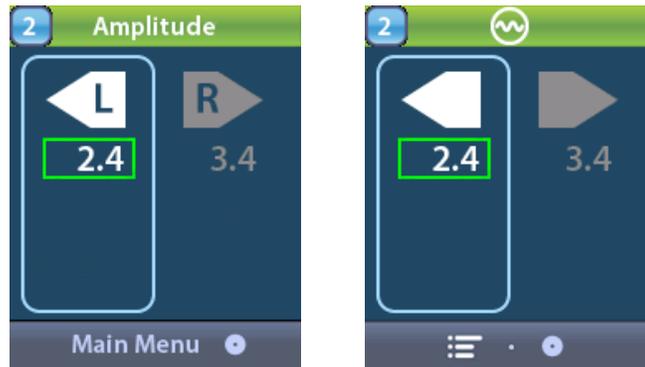
Changing Stimulation Level

A program may apply stimulation to one area, or up to four areas, depending on how the program is set up. The stimulation level for an area may be changed if allowed by the clinician using the Remote Control.

1. From the  **Main Menu**: Select  **Stimulation**.



2. Use the navigation buttons (   ) to select the desired area.



3. Press the Minus  button to decrease the level of stimulation.
4. Press the Plus  button to increase the level of stimulation.

Accessing System Settings

From the ☰ Main Menu:

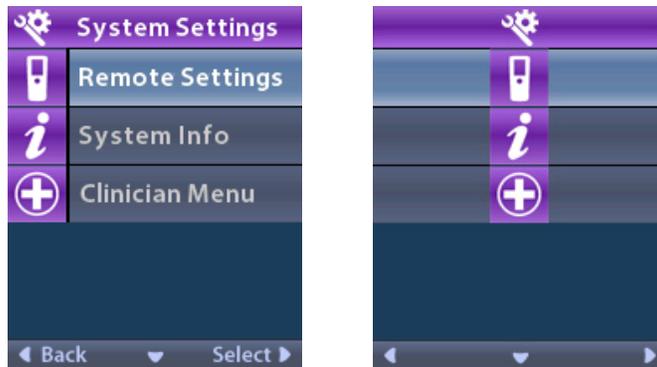
Select  **System Settings** to display the System Settings menu.

System Settings Menu for Rechargeable Vercise Gevia Stimulator



Note: When the Remote Control is linked to a Vercise Gevia rechargeable Stimulator, the Enter/Exit MRI Mode icon will appear on the System Setting screen. Refer to the MRI Mode section for information on the Enter/Exit MRI Mode feature.

System Settings Menu for Non-Rechargeable Stimulator



Note: When the Remote Control is linked to the non rechargeable Stimulator that is not MRI Conditional, the Enter/Exit MRI Mode option is not available.

Remote Settings

The Remote Settings option allows you to adjust the alert volume and screen brightness, and to select your language preference.

From the System Settings menu:

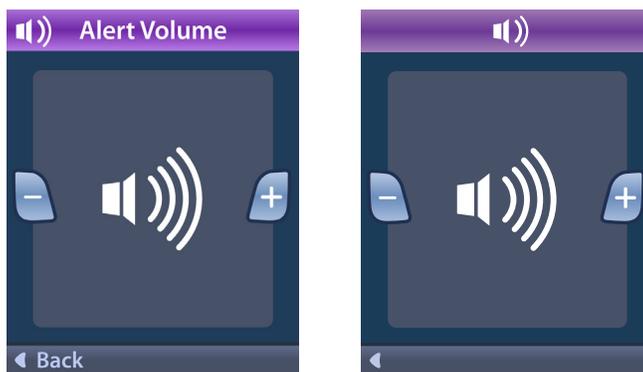
1. Select **Remote Settings** to display the **Remote Settings** menu.



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.

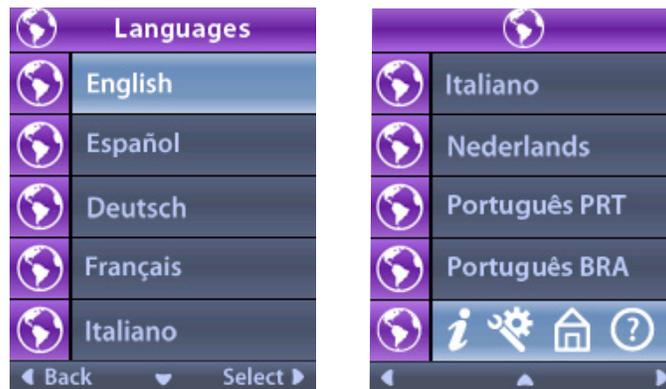
Languages

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

- Text screen in one of the available languages
- Iconic screen

From the **Remote Settings** menu:

1. Select  Languages.



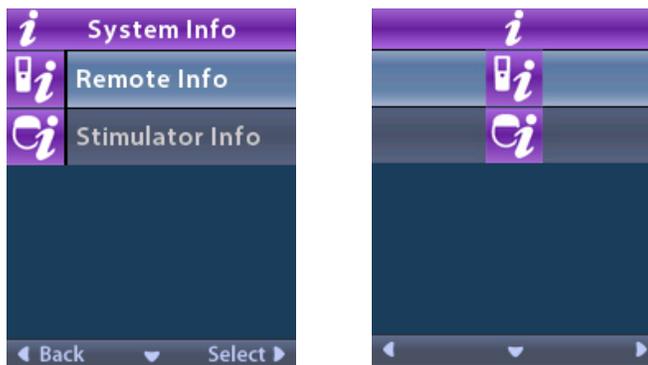
2. Select the desired language, such as  **English** or      iconic display. The Languages Confirmation screen displays to confirm your selection.



System Info

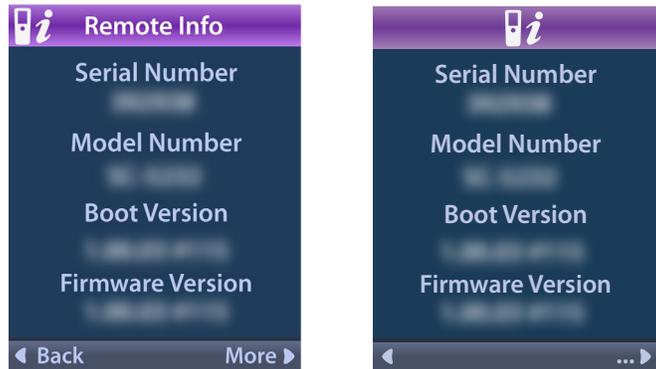
The **System Info** menu gives you the option of viewing information regarding the Remote Control or the Stimulator.

From the  **System Settings** menu, select  **System Info**.



Remote Info

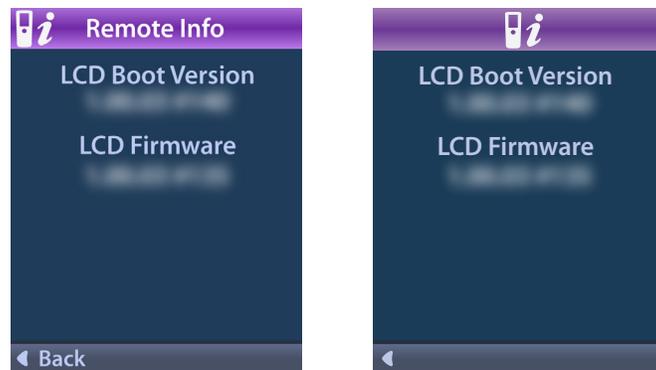
Select  **Remote Info** to view the Remote Info screen.



The Remote Info screen displays the following information:

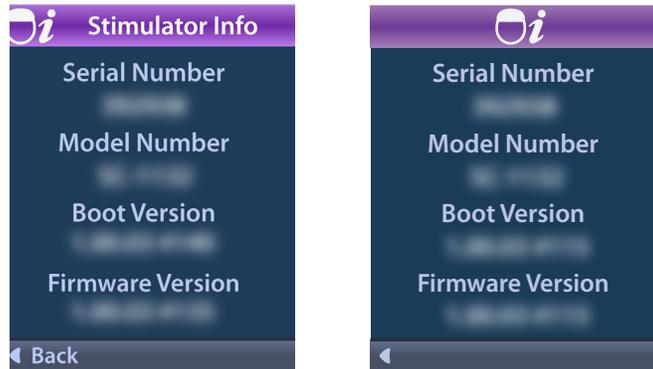
- Serial Number
- Model Number
- Boot Version
- Firmware Version

Select **More** to view additional Remote Info, such as LCD Boot Version and LCD Firmware.



Stimulator Info

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



The Stimulator Info screen displays the following information:

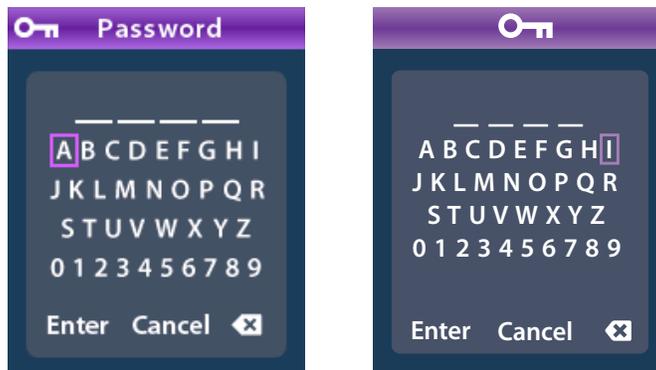
- Serial Number
- Model Number
- Boot Version
- Firmware Version

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. To enter the Clinician Menu you must enter a password. Contact your Boston Scientific representative for the Clinician Password.

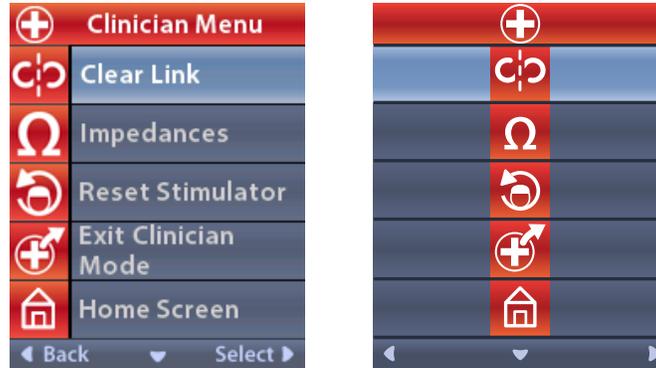
From the  System Settings menu:

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 Control is not linked to a Stimulator, the Stimulator Search option displays on the Clinician Menu instead of the Clear Link option.

Stimulator Search

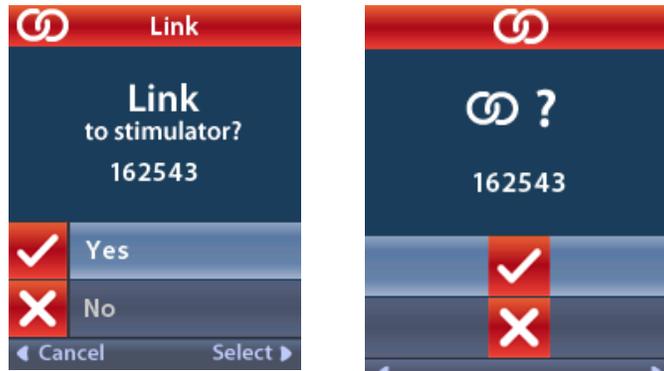
The Clinician Menu allows you to search for a Stimulator and link to it.

From the Clinician Menu:

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



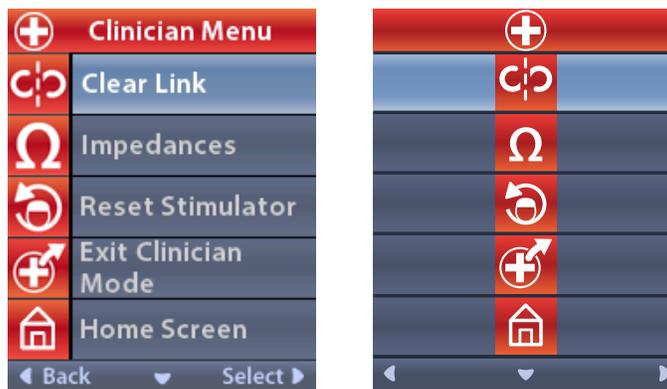
- If the desired Stimulator has not been located, select  Rescan.
- Select the Stimulator that you wish to link to. The  **Link to Stimulator ? #####** screen displays.



- Select  **Yes** to link to the Stimulator.
or
Select  **No** to cancel the action.

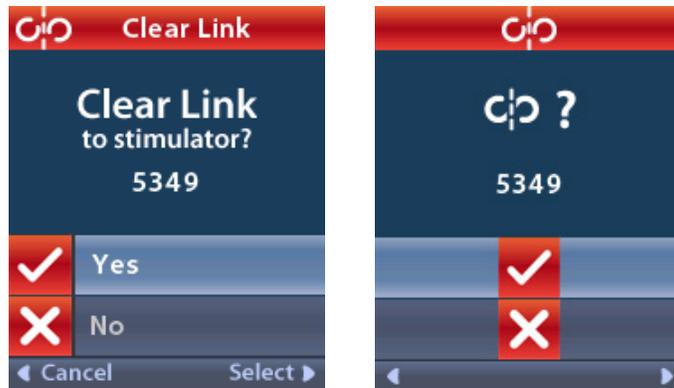
Clear Link

If the Remote Control 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.



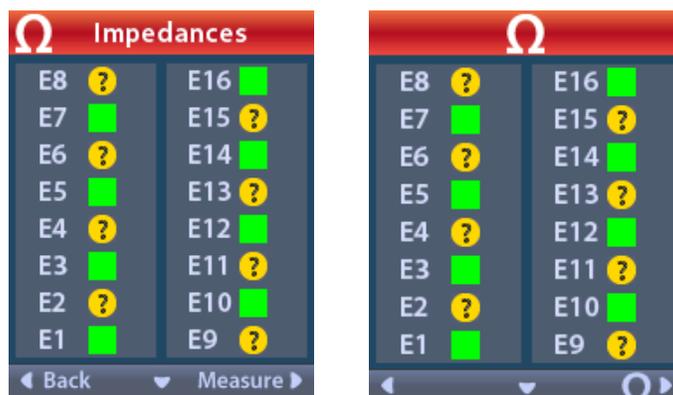
2. Select  **Yes** to clear the link to the Stimulator.
or
Select  **No** to cancel the action.

Impedances

You can use the Remote Control to check impedances.

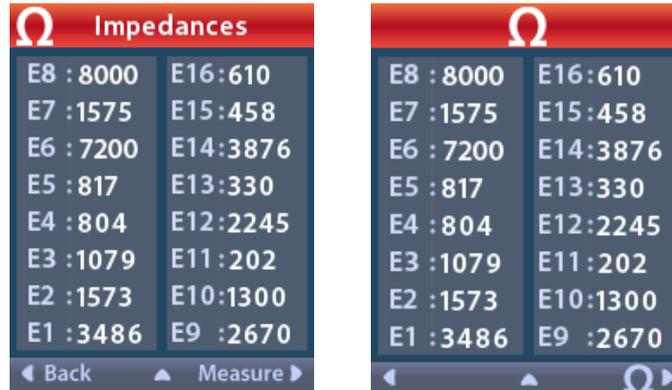
From the Clinician Menu:

1. Select  **Impedances**. An impedance measurement is taken and the Impedances screen is displayed.



When an impedance measurement is taken, impedances are assessed between a contact and the case (monopolar), and between pairs of contacts (bipolar). A green square indicates that impedance is within the acceptable range. A yellow dot with a question mark indicates that impedance is outside of the acceptable range.

Monopolar impedance values can be displayed by pressing the Down  Arrow button from the Ω Impedances screen.



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

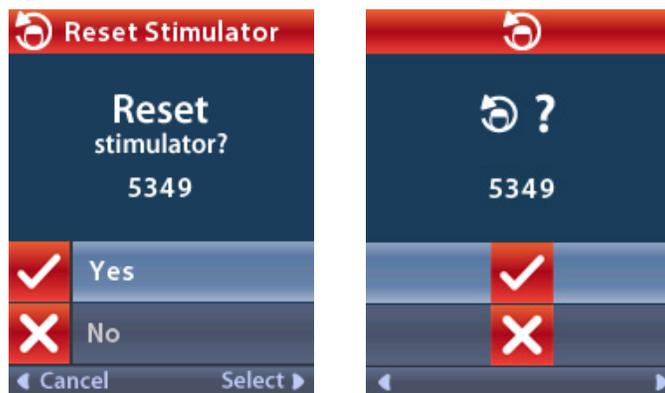
3. Select  **Back** to go back to the Clinician Menu.

Reset Stimulator

You can use the Remote Control to reset the Stimulator.

From the **Clinician Menu**:

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



4. Select **✓ Yes** to reset the Stimulator
or
Select **✗ No** to cancel the action.

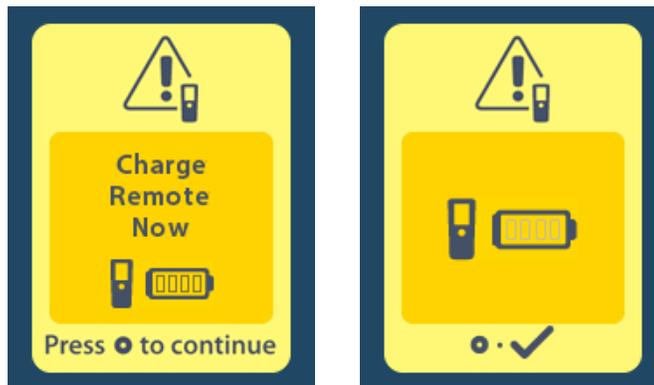
Exit Clinician Mode

From the Clinician Menu, select  **Exit Clinician Mode**. The System Settings screen displays.

Remote Control Battery

Remote Control Battery Status

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



Recharging the Remote Control

Recharge the Remote Control battery by connecting the remote control to the USB power supply provided with the Remote Control. The Remote Control battery has a typical service life of 400 charging cycles.



5. Press the **Right Arrow**  button to navigate to the **Main Menu**.
6. Select **System Settings** .

MRI Mode (For MR Conditional Rechargeable Vercise Gevia Stimulator Only)

A patient implanted with the Vercise Gevia DBS System can undergo an MR Conditional Scan when all instructions listed in the ImageReady™ MRI Guidelines for Boston Scientific DBS Systems are followed. Contact Boston Scientific Customer Support or go to www.bostonscientific.com/manuals for the latest version of this manual.

Enabling MRI Mode

When the Remote Control is linked to the Vercise Gevia rechargeable Stimulator, the Enter MRI Mode icon  will appear on the System Setting screen. The Remote Control must be used to enable MRI Mode on the Stimulator before performing an MRI scan on a patient. The stimulation is automatically turned OFF when MRI Mode is enabled.

Warning: *Do not perform an MRI scan if MRI Mode is not enabled. Scanning under different conditions may result in patient injury or device malfunction.*

To enable MRI Mode:

1. Unlock the Remote Control by pressing the **Lock/Unlock**  button on the right side of the Remote control.
2. After unlocking the Remote Control, the Home screen appears.

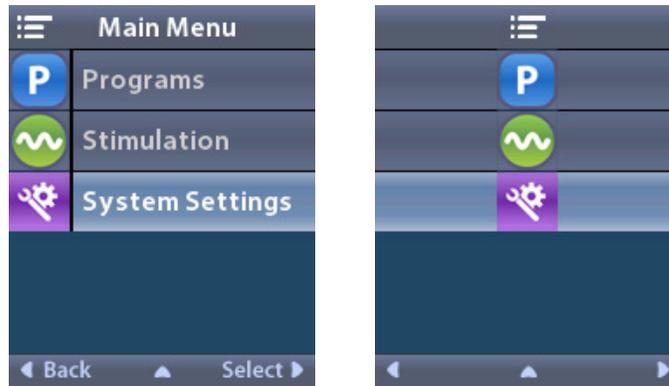


Note: *The Remote Control may display either a text screen in one of the languages provided or an iconic screen.*

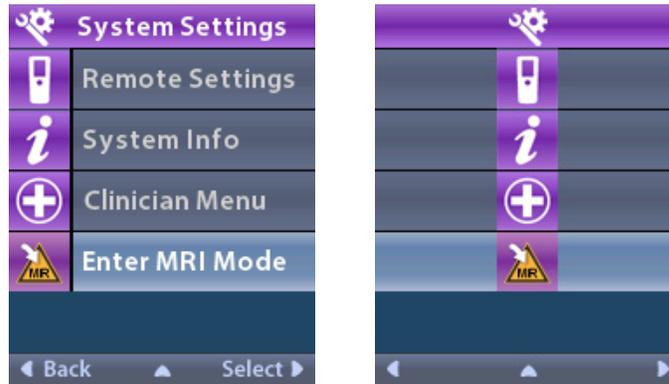
Vercise™ DBS Remote Control 3 Directions for Use

3. Press the **Right Arrow**  button to navigate to the **Main Menu**.

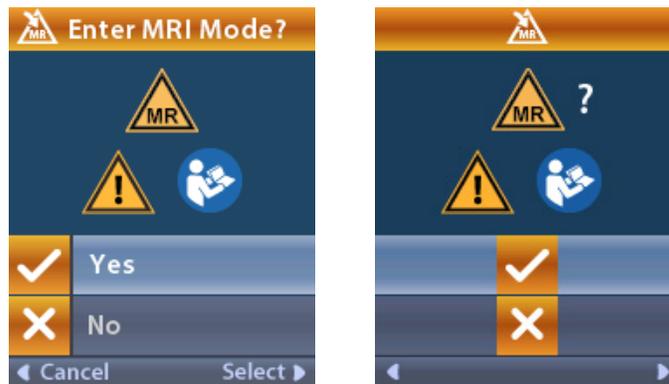
4. Select **System Settings** .



5. Select **Enter MRI Mode** .

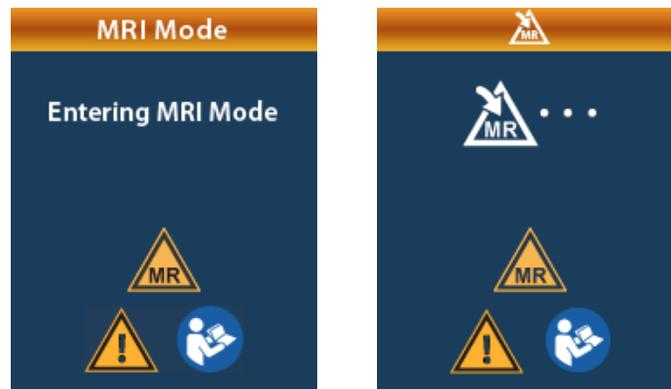


6. Select **Yes**  to enter MRI Mode or **No**  to cancel the action.

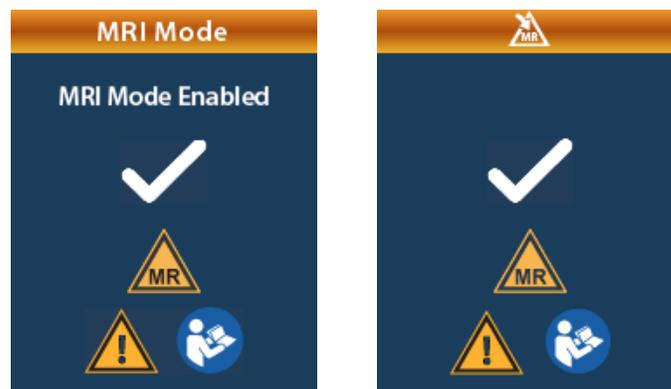


MRI Mode (For MR Conditional Rechargeable Vercise Gevia Stimulator Only)

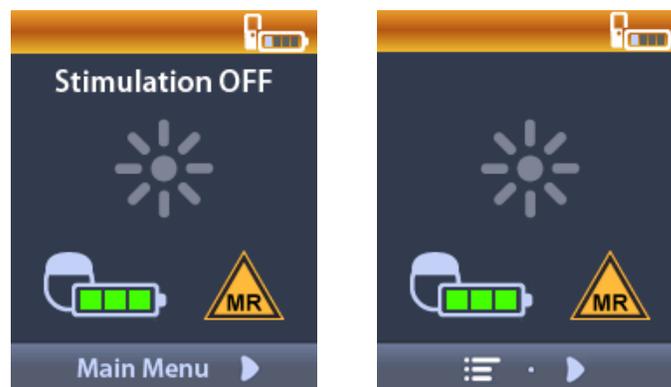
7. The Stimulator performs a series of checks before MRI Mode is enabled.



8. If MRI Mode is enabled, stimulation is turned OFF and the MRI Mode Enabled confirmation screen is displayed.



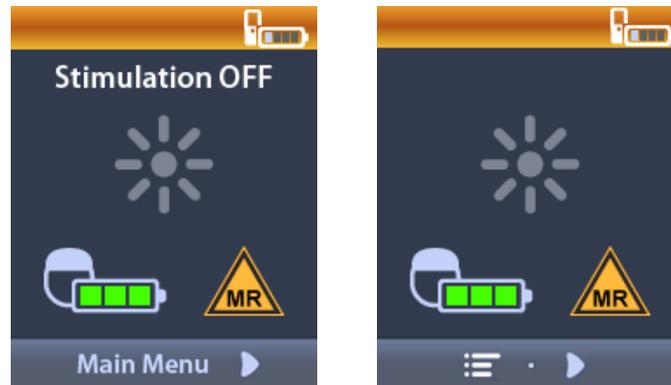
9. The Home Screen on the Remote Control will display the MR Conditional Symbol  if MRI Mode is enabled. Always confirm that the home screen of the Remote Control displays the MR Conditional Symbol before performing an MRI scan on the patient.



Disabling MRI Mode

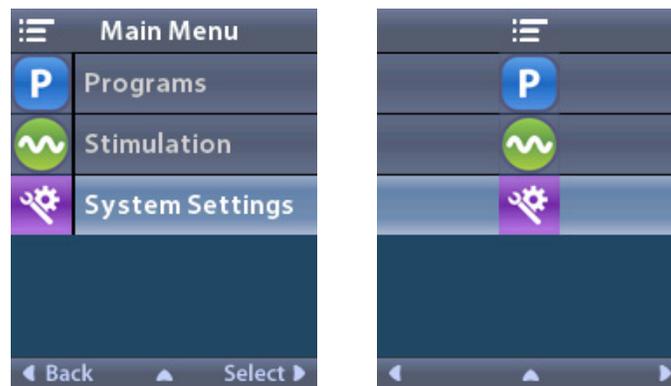
Upon completion of the MRI scan, the Remote Control must be used to disable the MRI Mode. To disable MRI Mode:

1. Unlock the Remote Control by pressing the **Lock/Unlock**  button on the right side of the Remote Control.
2. After unlocking the Remote Control, the Home screen appears.



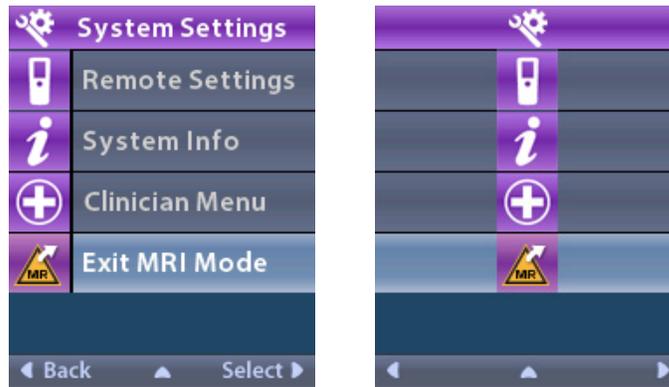
3. Press the **Right Arrow**  button to navigate to the **Main Menu**.

4. Select **System Settings** .

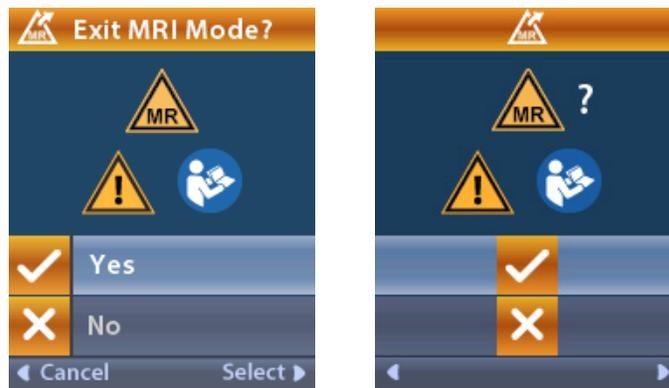


MRI Mode (For MR Conditional Rechargeable Vercise Gevia Stimulator Only)

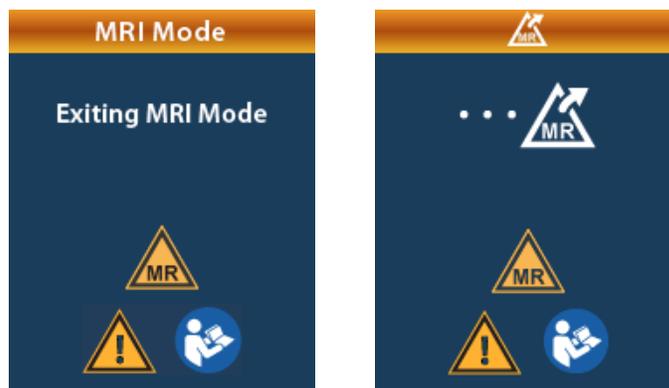
5. Select **Exit MRI Mode** .



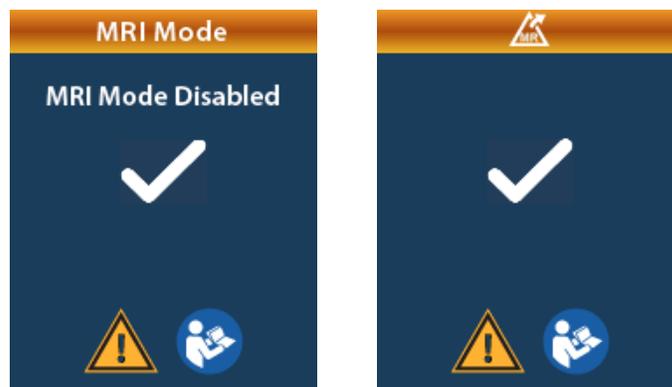
6. Select **Yes**  to Exit MRI Mode or **No**  to cancel the action.



7. The Stimulator performs a series of checks before disabling MRI Mode.



8. If MRI Mode is disabled, the MRI Mode Disabled confirmation screen is displayed.



Note: The Stimulator will retain the stimulation and program settings that were set before MRI Mode was enabled. If the stimulation was ON before MRI Mode was enabled, then disabling MRI Mode turns the stimulation back ON. If stimulation was OFF before MRI Mode was enabled, then disabling MRI Mode keeps the stimulation OFF.

9. The Home Screen on the Remote Control will not display the MR Conditional Symbol once MRI Mode is disabled.



MRI Mode Error Screens

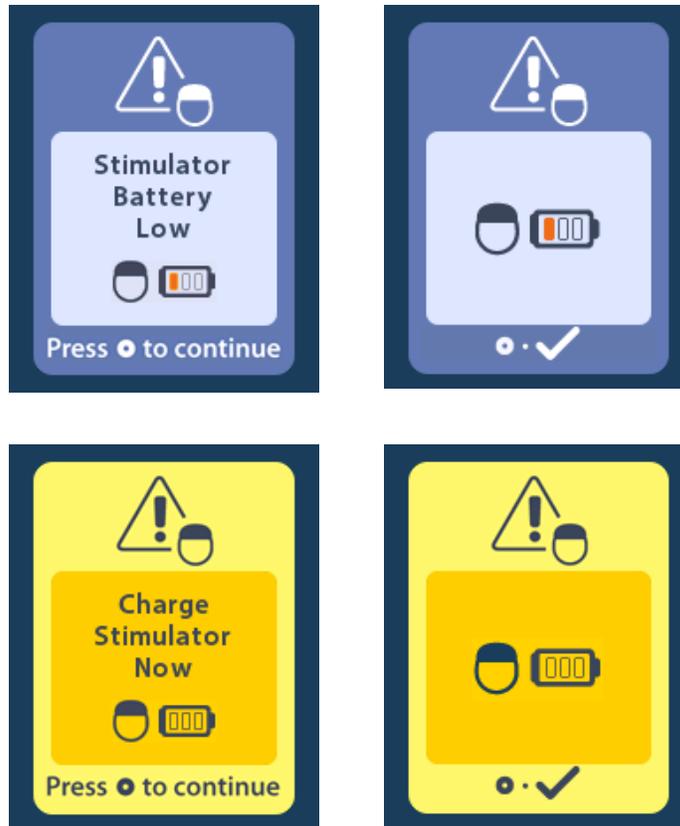
The Remote Control performs system checks once “Enter MRI Mode” is selected from the Systems Settings. It will display error screens if :

- The Stimulator battery is not fully charged.
- The Impedance check detects an anomaly.
- There is an error in the Stimulator.

MRI Mode (For MR Conditional Rechargeable Vercise Gevia Stimulator Only)

Charge Stimulator Now Screen

The Stimulator battery must be fully charged before the MRI Mode is enabled. If the Stimulator battery is not fully charged, the Remote Control will display one of the following messages instructing the patient to charge the Stimulator before enabling MRI Mode.

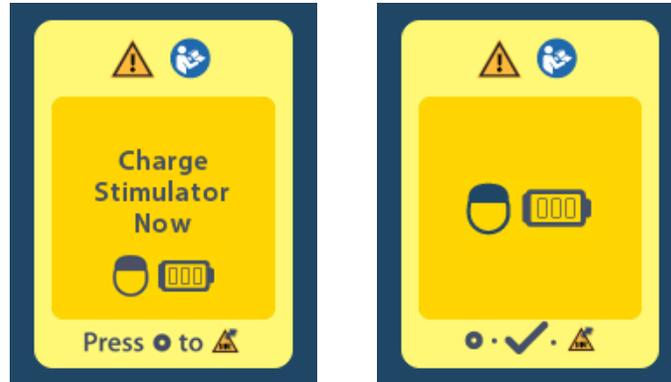


Warning: Always check the Stimulator battery to ensure that it is fully charged before performing a scan on the patient.

1. Press  to dismiss the error message and return to the Remote Control Home Screen.
2. Instruct the patient to charge the Stimulator.
3. Enable MRI Mode once the Stimulator is fully charged.

Charge Stimulator Now or Disable MRI Mode Screen

If MRI Mode has already been enabled and the Stimulator battery power falls below the recommended value, the Remote Control will display a message instructing the patient to charge the Stimulator.



To charge the Stimulator without disabling MRI Mode:

1. Do not press .
2. Instruct the patient to charge the Stimulator.
3. Check the Remote Control to confirm that the error message has cleared.
4. Navigate to the Home Screen on the Remote Control by pressing  on the side panel of the Remote Control and confirm that the MR Conditional Symbol  is displayed on the Home Screen.

The patient can also disable the MRI Mode before charging the Stimulator:

1. Press  to disable the MRI Mode.
2. Instruct the patient to fully charge the Stimulator.
3. Check the Remote Control to confirm that the error message has cleared.
4. Enable MRI Mode by following instructions in the Enabling MRI Mode section in this manual.

Caution: *Charger and Remote Control are MR Unsafe and must not be brought into the MRI scanner room.*

MRI Mode (For MR Conditional Rechargeable Vercise Gevia Stimulator Only)

Impedances Out Of Range Screen

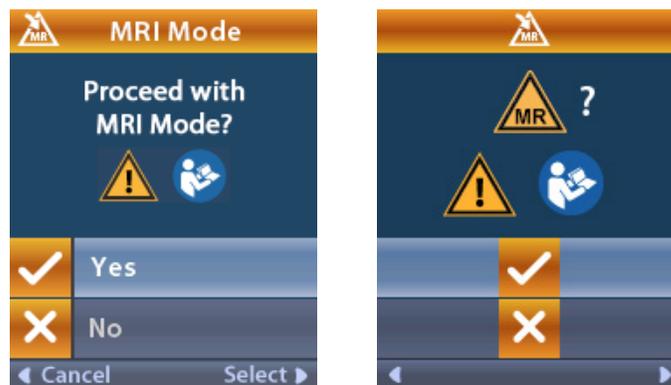
The impedances must be within the acceptable range before MRI Mode is enabled. If the impedances are not within the acceptable range, the Remote Control will display an error message.



1. Press  to continue.
2. The Remote Control displays a new message instructing the user to review the MRI scan risks related to abnormal impedances. Review the *Impedance Out of Range* section in the ImageReady™ MRI Guidelines before proceeding. Press  to continue.



3. Select **Yes**  to proceed with enabling MRI Mode or **No**  to cancel the action.



Warning: An MRI scan is not recommended when the impedances are not within the acceptable range. Higher or lower than normal impedances could indicate compromised Stimulator-Lead integrity. Scanning under these conditions may increase the risk of potential adverse effects listed in the Safety Information section of the ImageReady™ MRI Guidelines.

Stimulator Error Screen

If the system check fails due to a Stimulator error, MRI Mode will not be enabled and the Remote Control will display the Stimulator Error Screen. Do not perform an MRI scan if this error is displayed. Instruct the patient to contact their physician managing their DBS System or Boston Scientific.

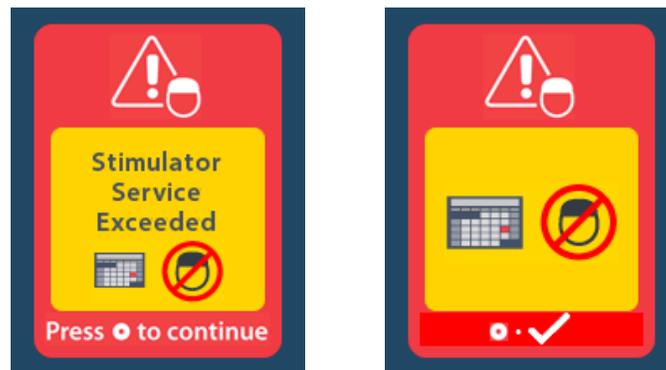


End of Programmed Service (For Non-rechargeable Stimulators Only)

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

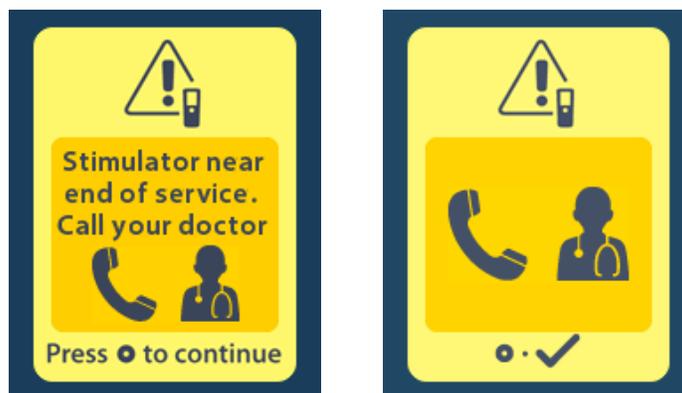


Press [stimulator icon] to clear the message. The message will reappear approximately weekly until the end of the non-rechargeable Stimulator's programmed period is reached. When the end of its programmed period is reached, the Remote Control will display the following on-screen message.



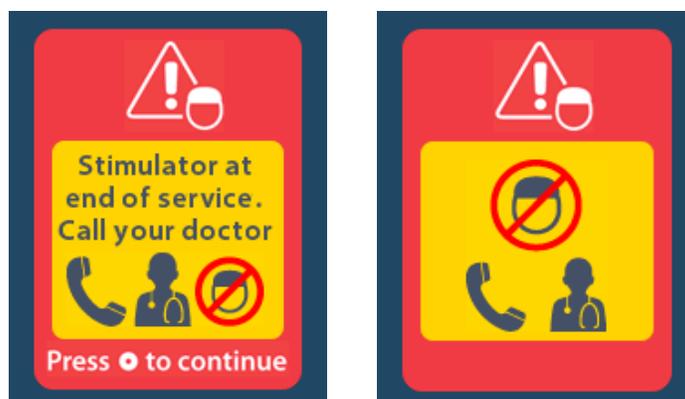
ERI (Elective Replacement Indicator) Screen (For Non-rechargeable Stimulator Only)

This screen displays when 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. Batteries that have lasted one year or more without entering ERI mode will have a minimum of four weeks between entering ERI mode and reaching end of battery life. Patients should be advised to contact their physician to report this message screen. Press  to clear this information screen. This screen will appear whenever the Remote Control is activated.



End of Battery Life Screen (For Non-rechargeable Stimulator Only)

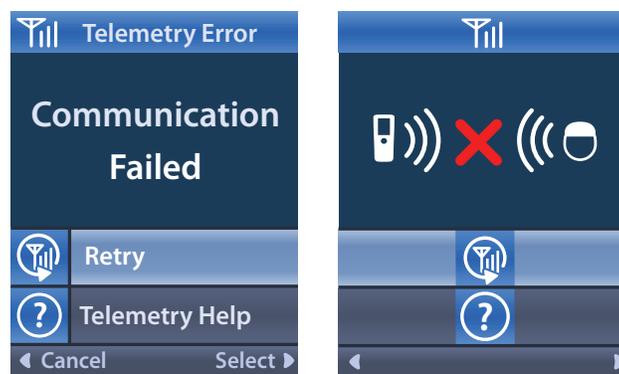
This screen displays when the battery of the implanted non-rechargeable Stimulator is fully depleted. Stimulation is not available. Patients should be advised to call their physician when this message appears.



Troubleshooting

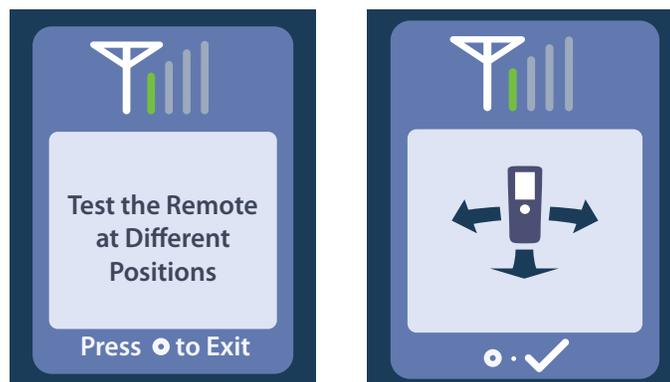
Telemetry Help

Common sources of interference, such as televisions and computer monitors, can affect wireless communication. You will continue to have access to the Remote Control menus even if the Remote Control 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 Remote Control 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 Remote Control 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 Remote Control and the Stimulator. To use the Telemetry Help tool, select Telemetry Help . The following screen will be displayed:

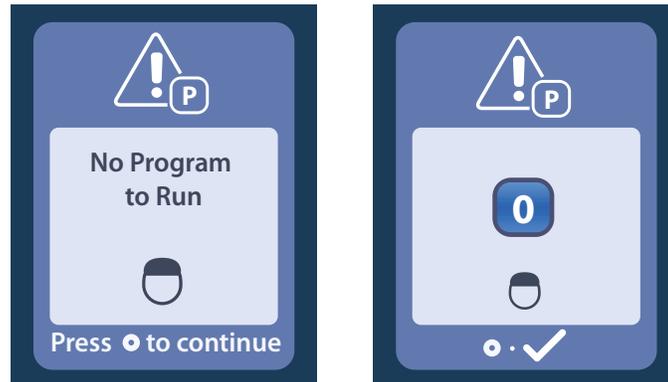


Vercise™ DBS Remote Control 3 Directions for Use

The telemetry bars indicate the strength of wireless communication. The number of bars will change depending on the distance and orientation of the Remote Control 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.



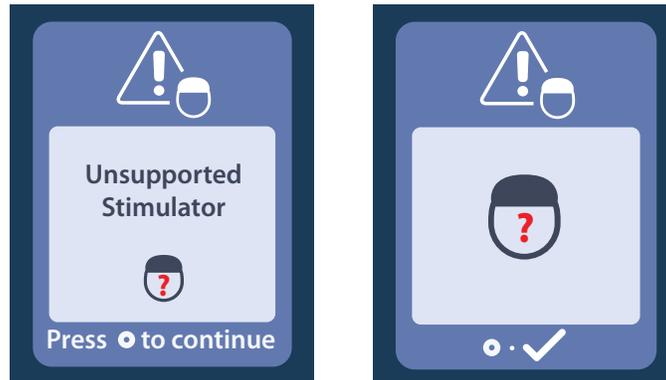
Invalid Program Screen

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



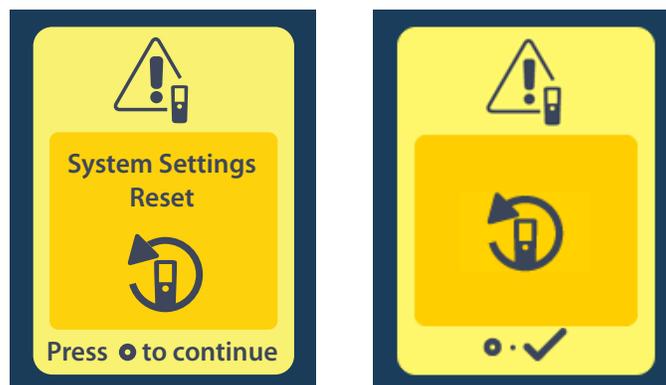
Unsupported Stimulator Screen

This screen is displayed when the Remote Control detects an incompatible Stimulator.



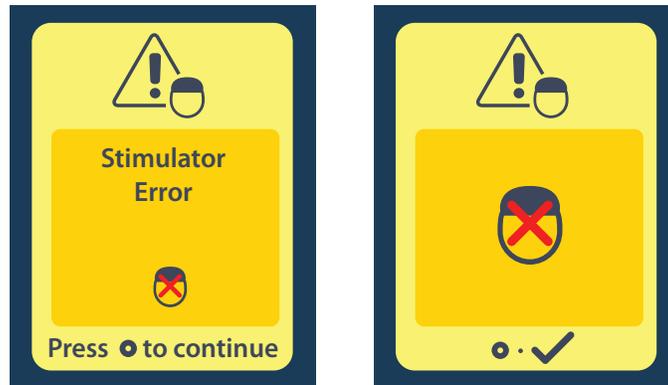
System Settings Reset Screen

This screen is displayed when the Remote Control experiences an error and a reset of the Remote Control is required. Press [button icon] to continue. Programs will not be deleted, but all system settings (for example, language and volume 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.



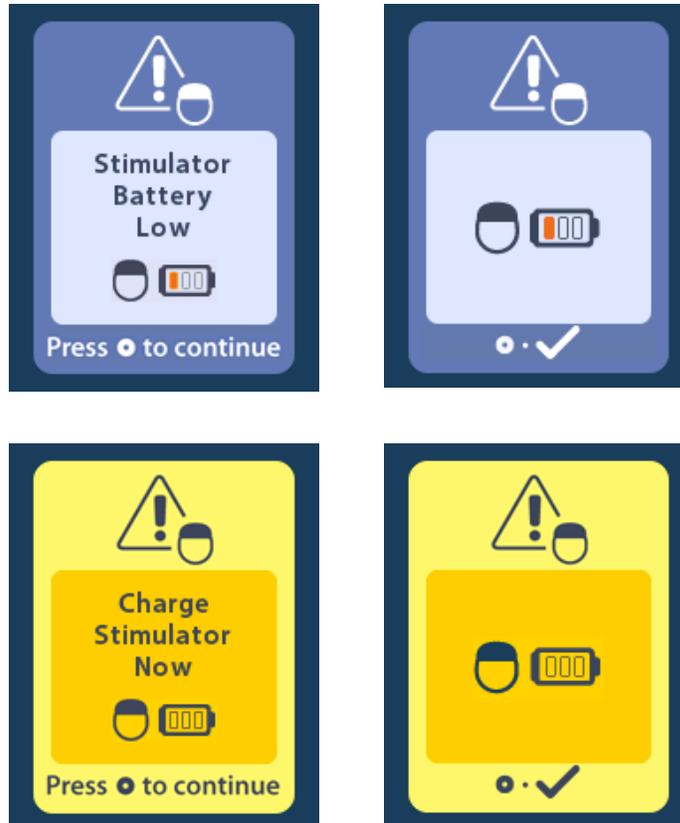
Remote Error Screen

This screen is displayed when there is a critical error on the Remote Control, which makes the Remote Control unusable. Please contact Boston Scientific to order a replacement Remote Control.



Stimulator Low Battery Screens (For rechargeable Vercise Gevia Stimulator only)

The Remote Control will display the following messages reminding you to recharge the Stimulator if the battery power is low.



Icon Description and Index

A



Alert Volume 9

C



Change Program 5



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Clinician Menu 13, 14, 15, 16, 17, 18

E



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System Settings 4, 8, 9, 11, 13, 18, 20, 22

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Legal Manufacturer

Boston Scientific Neuromodulation
Corporation
25155 Rye Canyon Loop
Valencia, CA 91355 USA
(866) 789-5899 in US and Canada
(661) 949-4000, (661) 949-4022 Fax
(866) 789-6364 TTY
www.bostonscientific.com
Email: neuro.info@bsci.com



Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666



EU Authorized Representative

Boston Scientific Limited
Ballybrit Business Park
Galway, Ireland
T: +33 (0) 1 39 30 97 00
F: +33 (0) 1 39 30 97 99

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