Vercise™ DBS Remote Control 3 Handbook

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

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<td>Vercise DBS Remote Control 3 Kit</td>
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<td>DB-5250-S</td>
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<tr>
<td>NM-6210</td>
<td>Remote Control Holster</td>
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<tr>
<td>NM-6315, NM-6310</td>
<td>USB Power Supply</td>
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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.

Drawings are for illustration purposes only.

**Additional Information**
Refer to the Information for Patients manual for additional information on your Deep Brain Stimulation System, such as indications for use, contraindications, warnings, precautions, adverse effects, storage and handling, device disposal, and information for contacting Boston Scientific. For charging instructions for rechargeable Stimulators, refer to the Vercise DBS Charging Handbook.

**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.
This manual has been color-coded to help you use the Remote Control while referencing the manual.

Each section is labeled and color-coded
Introduction

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.

The Remote Control is a hand-held device that allows you to communicate with your Stimulator. Typically, you will be using the Remote Control to turn stimulation ON or OFF.

Your Remote Control will also display important messages about your Stimulator and Remote Control battery status. You should check your Remote Control at least once per month.
Remote Control Buttons

Buttons are located on the front and sides of the Remote Control as shown in the picture.

On the right side of the Remote Control, you will find the Lock/Unlock button. On the left side, you will find the HOME button and Programs button P.

On the front of the Remote Control, you will find the Stimulation ON/OFF button, and the Decrease (-) and Increase (+) buttons that allow you to adjust features, such as the Remote Control volume and brightness. Below the Stimulation ON/OFF button are the Navigation buttons, which allow you to navigate through various menus.
Remote Control Screen

The Remote Control screen displays menus, icons, status messages, error messages, and other information.

When the Remote Control is not in use (for example, the buttons are not being pressed), the screen automatically darkens after approximately 1 minute to preserve the Remote Control’s battery. The screen lights up when the Remote Control is unlocked and remains on while the Remote Control is being used. To change the brightness of the screen, see About System Settings.

Typically, when the Remote Control is in use, the Home screen displays.
The Home screen indicates whether stimulation is ON 🌟 or OFF 🌟. If you have a rechargeable Stimulator, the Home Screen will also display the current battery level of the Stimulator.

Icons at the top of the Home screen indicate the charge level of the Remote Control battery 🇺🇸, and the number of the Program currently running.

**Non-Rechargeable Stimulator**

- Program Number
- Remote Control Battery Level

**Rechargeable Stimulator**

- Stimulation ON
- Stimulator Battery Level

**Note**

Pressing the Home button 🏡 from almost all other screens will return you to the Home Screen.
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Quick Start Guide

1. Unlock

2. To turn Stimulation ON press 🌞

3. To turn Stimulation OFF press 🌞
To access the Main Menu press

Lock

QUICK START
Stimulation can be turned ON and OFF by pressing the Stimulation ON/OFF button 🔄. To turn stimulation ON or OFF, you must unlock the Remote Control first; then, press the Stimulation ON/OFF button.

To START/STOP stimulation, press ✅

Note

Stimulation will not automatically turn OFF when the Remote Control is locked or when the screen darkens to preserve power in the Remote Control battery.
Recharging the Remote Control

The Remote Control displays messages reminding you to recharge the battery when the battery power is low.

Recharge the Remote Control battery by connecting the Remote Control to the USB Power Supply provided. Connect the power plug end of the USB Power Supply to a power outlet.

The Remote Control has a typical battery service life of 400 charging cycles.
The following accessories are provided with the Remote Control:

**Silicone Case** - The Silicone Case allows you to customize your Remote Control. You can access all the buttons, the USB port, and see the screen while the device is in the Silicone Case. The side buttons that are covered by the Silicone Case are still available for use.

**Holster** - The Remote Control holster allows you to carry the Remote Control on a belt. You can only access the Stimulation ON/OFF button and the USB port of the Remote Control while it is enclosed in the holster.

CAUTION

Always place the Remote Control in the Silicone Case so that the Stimulation button is on the open side of the case and remains uncovered.
**USB Power Supply** - The USB Power Supply is used to recharge the Remote Control battery. Connect the USB connector on the Power Supply to the Remote Control. Then, find a convenient electrical outlet that will not expose the Remote Control or Power Supply parts to water or direct heat. Connect the power plug on the Power Supply to a power outlet. The USB port on the Remote Control is designed to accept a standard 5V Mini-B USB power supply.
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How To Use Programs

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What Is a Program?

A Stimulation Program is a group of configured settings that produce the stimulation to help you manage your symptoms. One or more Programs were configured by your physician. Whenever you are using your Stimulator, one of these Programs is active, and stimulation is delivered according to the configured settings. The Remote Control can store up to four programs – numbered 1 through 4 – for you to select and activate at any time. Each Program is identified by a number.

Each Program may apply stimulation to as many as four stimulation areas. For example, one area may correspond to a right brain target, while another area may correspond to a left brain target. These stimulation areas control additional parameters that can affect your stimulation therapy.
Changing Stimulation Level

Physicians may allow certain patients to change the stimulation level of individual areas of a program. If your physician allows you to change your stimulation level, you may adjust stimulation level from the Main Menu. Select Stimulation and then select the amplitude that you wish to change.

Use the − or + button to adjust stimulation. On the Amplitude screen, L corresponds to the left side of the body and R corresponds to the right side of the body. If you adjust stimulation to the limit of the allowable range, the “Limit Reached” screen will appear. Press the button to return to the Main Menu.
Accessing Programs

If your physician has configured Programs that can be changed, there are two ways to view the Programs menu:

- Press the Programs button $P$ on the left side of the Remote Control.
- From the Main Menu $\equiv$, select Programs $P$ by pressing $\circ$.

Note
After entering the Main Menu $\equiv$, the $\circ$ button can also be pressed to make a selection.
Overview of the Programs Menu

If your physician has configured Programs that can be changed, you can do any of the following operations:

- Turn Stimulation ON/OFF and adjust stimulation level for the Program currently running
- Change the currently running Program to a different Program (if available)
- Restore a Program to the settings that your healthcare provider last configured for you

If any changes were made to your stimulation (for example, changing stimulation strength), the changes will save automatically.
Change to a Different Program

1. From the Home Screen, press 📣 to display the Main Menu 📜.

2. Press ⬆️ again to enter the Programs menu 🅰️.

3. Press ⬆️ again to enter the menu 🅰️.
Press ▼ to select the desired Program.

Press ▻ to activate the selected Program.
Restore a Program

If you decide that you want to change the Program back to the way it was configured by your physician, you can do so by restoring the Program.

1. From the Main Menu ☐, press ☐ to select Programs ☐.

2. Press ☐ to highlight Restore to Clinic Settings ☒. Press ☐ to select.
The Screen displays all Programs configured by your physician. Navigate to the Program you wish to restore and press ✅.

Select Yes ✅ to restore the program or No ❌ to cancel.

The Restore confirmation screen displays.
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About System Settings

Using the System Settings, you can set or change a Remote Control interface settings, like Alert Volume, Screen Brightness, and the Language setting.

In addition, you can view information about the Remote Control and the Stimulator. Your physician can access special functions through the Clinician Menu (password protected) to aid you in your therapy.

If you are implanted with a Vercise Gevia rechargeable Stimulator, the Enter or Exit MRI Mode icon will appear on the System Setting screen. Refer to MRI Mode section for information on MRI Mode.
Adjust Screen Brightness

1. From the Main Menu , select System Settings .
2. Select Remote Settings by pressing .
3. Select Screen Brightness by pressing .
4. To decrease or increase Screen Brightness, press the or the button.
Adjust Volume

The Remote Control emits a single, short “beep” whenever you press a button. The volume of the alert can be adjusted or turned off.

1. From the Main Menu, select System Settings.
2. Select Remote Settings by pressing .
3. Select Alert Volume ( ) by pressing .
4. To increase or decrease screen volume, press the or the button.
View Information about Your Remote Control or Stimulator

You can view basic information about your Remote Control and Stimulator that may be helpful for your physician when troubleshooting an issue.

1. From the Main Menu, select System Settings.
2. Select System Info \( \text{i} \) by pressing \( \text{ } \).
3a. Select Remote Info \( \text{i} \) by pressing \( \text{ } \).
3b. Select Stimulator Info \( \text{i} \) by pressing \( \text{ } \).
About MRI Mode  
(For Rechargeable Vercise Gevia Stimulator Only)

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If you have a Vercise Gevia rechargeable Stimulator, you must use the Remote Control to enable MRI Mode on the Stimulator before an MRI scan is performed and exit MRI Mode after the MRI scan has been completed. The Stimulator battery must be fully charged before MRI Mode is enabled.

Your physician and MRI center must ensure all guidelines listed in the ImageReady™ MRI Guidelines for Boston Scientific DBS Systems are followed before an MRI scan is performed. Ask your physician or MRI center to contact Boston Scientific Customer Support or go to www.bostonscientific.com/manuals for the latest version of the ImageReady MRI guidelines manual.

Note
Always carry your Remote Control and Charger to the MRI center. The Remote Control and Charger are MR unsafe and must not be taken inside the scan room.
Enabling MRI Mode

1. From the Home Screen, select 🔄 to display the Main Menu 📊.
2. From the Main Menu, select System Settings 📊.
3. Press 🔄 to navigate to the Enter MRI Mode 📊 option and then press 🔄.
4. Select ✅ Yes to enter MRI mode or ❌ No to cancel the action.
The Stimulator performs a series of checks before MRI Mode is enabled.

The MRI Mode Enabled confirmation screen displays and Stimulation is turned OFF.

The Home Screen will display the MR Conditional Symbol when MRI Mode is enabled. Always check the MRI Home screen before entering the MRI scan room.

CAUTION

The Remote Control is MR Unsafe and must not be taken into the MRI Scanner Room

Note

Stimulation is automatically turned OFF when MRI Mode is enabled.
Disabling MRI Mode

Upon completion of the MRI scan, the Remote Control is used to disable MRI Mode.

1. From the Home Screen, select 🌞 to display the Main Menu ☢️.
2. From the Main Menu, select System Settings 🔧.
3. Press ⌛️ to navigate to the Exit MRI Mode ⚠️ option and then press 🕒.
4. Select ✔️ Yes to exit MRI mode or ✗ No to cancel the action.
Note
The Stimulator retains the settings that were set before enabling MRI Mode. If stimulation was ON before MRI Mode was enabled, then disabling MRI Mode turns stimulation back ON. If stimulation was OFF before MRI Mode was enabled, then disabling MRI Mode keeps stimulation OFF.

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

MRI Mode disabled confirmation screen displays.

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

**CAUTION**
The Charger is MR Unsafe and must not be taken into the MRI Scanner Room.

**Note**
Always make sure to fully charge your stimulator before an MRI scan. Depending on the Stimulator battery level, it may take a few hours for your Stimulator to be fully charged.

**Charge Stimulator Now Screen**
The Stimulator battery must be fully charged before MRI Mode is enabled. If the Stimulator battery is not fully charged, one of the following messages will display.

Press to dismiss the error and charge the stimulator without enabling MRI Mode. Enable MRI Mode after the stimulator is fully charged.
Charge Stimulator Now or Disable MRI Mode Screen

A Charge Stimulator Now error message also appears when MRI Mode is enabled and your Stimulator battery level falls below the recommended value.

You can either disable the MRI Mode before charging your Stimulator or charge your Stimulator without disabling MRI Mode.

Disable the MRI Mode before charging your Simulator

Press \( \bullet \) to disable MRI Mode. Charge your stimulator and enable MRI Mode after the error message has disappeared and your stimulator is fully charged.

OR

Charge your Stimulator without disabling MRI Mode

Do not press \( \bullet \) and charge your stimulator. The error message disappears after your stimulator is fully charged. Make sure the Home Screen still displays the MR Conditional symbol \( \Delta \) before performing an MRI.
MRI Mode Error Messages

Impedances out of Range Screen
On enabling MRI Mode, the system performs a check of lead impedances. If the impedances are not within the acceptable range, the Remote Control will display an error message.

Press to acknowledge the message.
Press 🔄 to acknowledge the message.
Your physician or healthcare provider must check the integrity of the leads and review the risks listed in the Physician Manual ImageReady™ MRI Guidelines for Boston Scientific DBS Systems before proceeding with an MRI scan.

Select ✔ Yes after Physician approval to Proceed with Enabling MRI Mode or ✗ No to cancel the action.
MRI Mode Error Messages

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. Your physician should not perform an MRI scan if this error is displayed. Contact the physician managing your DBS System or Boston Scientific.
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Stimulator Low Battery Messages - Rechargeable Stimulators Only

For a rechargeable Stimulator, the Remote Control will provide on-screen messages to remind you when your Stimulator battery is low. One of the following messages will display:

For instructions on charging your Rechargeable Stimulator, refer to the Vercise DBS Charging Handbook.
Remote Control Low Battery Message

The Remote Control will provide on-screen messages to remind you when your Remote Control battery is low. The following messages will display:

Refer to Recharging the Remote Control section for more information on charging your Remote Control.
Charging Remote Screen

This screen is displayed when the Remote Control is being used and the USB power supply is plugged in.

Charger Disconnect Screen

This screen is displayed when the Remote Control is being used and the USB power supply is disconnected.
Remote Battery Full Screen

This screen is displayed when the Remote Control is being used and the remote battery becomes fully charged.

Button Stuck

If a button is stuck on the Remote Control, other button presses may not function as intended. The Remote Control will provide the following on-screen message if it detects a stuck button:

Refer to the instructions for cleaning the Remote Control in your Information for Patients Manual. If the button is still stuck, contact Boston Scientific.
End of Programmed Service - Non-Rechargeable Stimulators Only

The software for non-rechargeable Stimulators has been programmed to end service after a defined period. If your 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 \( \boldsymbol{\text{C}} \) to clear the message. The message will re-appear 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 Screen - Non-Rechargeable Stimulators Only

When the battery of a non-rechargeable Stimulator is nearing depletion, it will enter Elective Replacement Indicator (ERI) mode and will display the following message: “Stimulator near end of service. Call your doctor.” Surgery is required to replace the implanted non-rechargeable Stimulator.

Call your physician to report the ERI message screen. Press to clear this information screen. This screen will appear whenever the Remote Control is activated.
When the battery of an implanted non-rechargeable stimulator is fully depleted, the Remote Control will display the following EOS message: “Stimulator at end of service. Call your doctor.”

Stimulation is not available. Surgery is required to replace the implanted non-rechargeable Stimulator.

The Home Screen will also display the EOS indicator icon.
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Telemetry Help

The Remote Control has an average communication range of 22 inches (55.8 cm) with the non-rechargeable Stimulator and an average communication range of 36 inches (91.4 cm) with the rechargeable Stimulator.

When using the Remote Control, avoid common sources of interference, such as televisions and computer monitors. These can affect wireless communication. You will continue to have access to the Remote Control menus even if it 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” and display the requested change.
If the Remote Control is unable to communicate with the Stimulator, the Telemetry error message, “Communication Failed,” will appear:

To retry communication with the Stimulator select Retry 🔄. This resends the last command. To cancel communication and return to the System Settings screen, press 🛑.
Telemetry Help

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:

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.
Unlinked Remote Control

The Remote Control and Stimulator must establish a one-to-one link in order to communicate. This prevents a Remote Control from accidentally communicating with another Stimulator. If your Remote Control is not linked to your Stimulator (i.e., when you have a brand new Remote Control), the following screen will appear and will prompt you to link the Remote Control to the Stimulator:

Please contact your physician if you see this message. Your physician can access special functions through the Clinician Menu to link your Remote Control to your Stimulator.
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 to continue. All Remote Control settings will be restored to the default factory settings.
Stimulator Error Screen

The Stimulator Error is a non-critical 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 or your physician to order a replacement Remote Control.
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