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# Vercise™ DBS Patient Manual

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℞ ONLY 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.

## Trademarks

All trademarks are the property of their respective holders.

## Additional Information

For charging instructions for rechargeable Stimulators, refer to the Vercise DBS Charging Handbook.

## Product Model Numbers

| Model Number | Product Name |
|---|---|
| DB-5500-1 | Vercise Remote Control Kit |
| NM-6600 | Travel Case |

## Patient Identification Card

Ensure you have received your Temporary Patient Identification Card. If not, please call your healthcare professional. Keep your Temporary Patient Identification Card with you until you receive your permanent card.

# User Assistance Information

**Important Numbers**

Physicians

Neurosurgeon _____

Neurologist _____

Caregiver _____

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(661) 949-4000, (661) 949-4022 Fax
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# Patients, Family Members, and Caregivers

Please be aware of the following:

- We advise you to read this entire patient manual so that you understand its contents. It is unsafe to start using the device before reading the whole manual. If you have any questions, or need clarification of anything contained in this manual, please contact your physician.
- Always inform any medical staff that you have been implanted with a brain stimulation device. If medical personnel have any questions, they should contact Boston Scientific Technical Support at the number provided in *User Assistance Information*.
- If you have any questions or problems, please use the information on the previous page to contact your physician. In most cases, please contact your neurologist, as they are most likely to be able to resolve the issue. If any medical personnel have questions or concerns, please have them contact Boston Scientific Technical Support. If there is an emergency, call 911 or local emergency services.

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# Glossary

**Adhesive Patch.** Non-reactive and Latex-free skin patch designed to temporarily attach the Charger to the skin over the Stimulator site.

**Adverse Event.** Undesirable effect.

**Amplitude.** The measure of strength of delivered stimulation. (See “Level”).

**Base Station.** A holder/power supply that supports the Charger and keeps it in a ready state for recharging the Stimulator.

**Battery.** The rechargeable power source for your Stimulator. You should expect to recharge your Stimulator’s battery for 15 to 30 minutes daily or a periodic recharging time of 3 to 4 hours every 1 to 2 weeks, but your recharge routine may vary depending on your stimulation parameters.

**Cardiac Pacemaker.** A small implantable device used to control the rhythm of the heart.

**Charger.** A portable device used to recharge the battery of the implanted Stimulator.

**Charging Collar.** A garment used to hold the Charger over the Stimulator for proper charging.

**Charging Spacer.** A piece of material placed behind the Charger in the pocket of the Charging Collar, if directed by your physician.

**Charging System.** The Charging System consists of a Base Station, Charger, Power Supply, Charging Collar and Adhesive Patches. The Charging System is used for recharging the Stimulator.

**Contacts.** Metal electrodes on the DBS Lead that deliver electrical stimulation pulses to the brain.

**Contraindication.** A condition under which the device should not be used because the risks outweigh any possible benefit.

**Control Buttons.** Buttons located on the Remote Control used for adjusting stimulation settings.

**Counterweight.** A device placed in the Charging Collar on the opposite side of the Charger to balance the garment.

**DBS Lead.** An insulated wire that allows electrical stimulation pulses to be delivered from the Stimulator to the brain.

**Deep Brain Stimulation (DBS).** A method of applying electrical pulses to the brain to deliver therapy for various disorders.

**Diathermy.** A therapeutic procedure used to heat body tissue by high-frequency electromagnetic currents or ultrasound.

**Display.** The Remote Control screen that displays information about your Vercise™ DBS System.

**Electrical Stimulation.** Electrical pulses created by the Stimulator.

**Electromagnetic Interference.** Electromagnetic signals that interfere with a variety of electrical signals, including those used in deep brain stimulation.

**Fluoroscopy.** An x-ray procedure used during surgery.

**Hibernation Mode.** A state your Stimulator reaches when the battery level is too low to apply stimulation.

**Idle Mode.** A time-out period when the Remote Control is not being used. Also known as Sleep Mode.

**Implantable Cardioverter Defibrillator (ICD).** A small implantable device used to treat sudden cardiac arrest and to restore a normal heartbeat.

**Incision.** Small surgical cut or opening in the skin.

**Indicator Light.** A signal light on the Charger used to show the status of the Charger.

**Level.** Term used on the Remote Control screen to identify the amplitude or strength of stimulation.

**Magnetic Resonance Imaging (MRI).** A technique that uses magnetic fields and radio waves linked to a computer to create pictures of areas inside the body.

**Paresthesia.** A tingling sensation.

**Patient Identification Card.** A wallet size card that lists the patient and physician names, and the Stimulator model and serial number.

**Precaution.** Generally, situations that you should be aware of in order to avoid potentially undesirable stimulation effects and/or damage to your Vercise™ DBS System.

**Program.** A set of parameters that define the pattern of your stimulation.

**Remote Control.** A battery-powered hand-held programmer used to adjust stimulation.

**Save.** The Remote Control button command used to store a newly created or modified stimulation program.

**Sleep Mode.** A time-out period when the Remote Control is not being used. Also called Idle Mode.

**Stimulation.** Low level electrical pulses applied to the brain.

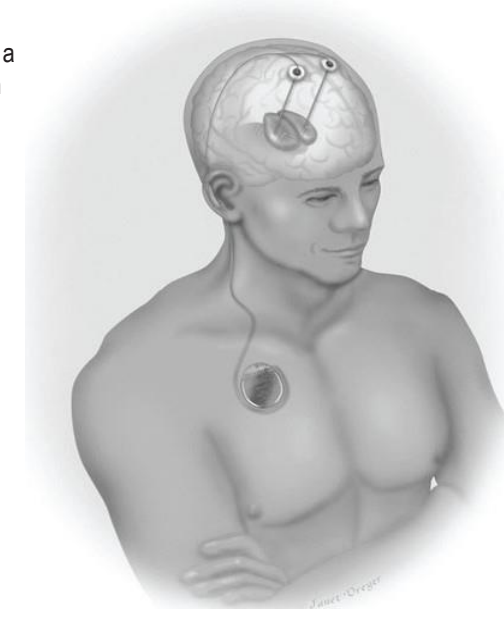
**Stimulator.** A device used to send electrical pulses to the brain. (Also referred to as the “Battery” or “Implantable Pulse Generator”).

**Ultrasound.** The use of high frequency sound waves to visualize structures inside your body.

**Warning.** Potential hazards that you must be aware of to avoid serious situations that may cause injury or death.

# Introduction

The Boston Scientific Vercise™ DBS System is used to treat Parkinson's disease through deep brain stimulation (DBS). DBS is a reversible therapy where structures in the brain are stimulated with small electrical pulses.



# Descriptive Information

## Intended Use / Indications for Use

The Vercise™ Deep Brain Stimulation (DBS) System is indicated for use in bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.

## Description of the Device

The Vercise DBS System includes both implantable and external components. The implanted portion of your Vercise DBS System has three main components:

- The **DBS Leads** are thin, insulated wires that can carry electrical signals to any of eight contacts implanted within the brain and deliver stimulation to the brain tissue. The rest of the DBS Leads lie underneath the scalp and connect to the DBS Extension connector, typically behind the ear.
- The **DBS Extensions** are thin, insulated wires that connect the DBS Leads to the Stimulator. The DBS Lead is inserted into one end of the DBS Extension. The connection between the DBS Lead and DBS Extension will typically be placed behind your ear. The other end of the DBS Extension lies beneath the skin and is inserted into the Stimulator. The DBS Extension transfers the electrical stimulation from the Stimulator to the DBS Lead.

- The **Stimulator** contains a rechargeable battery that supplies power to your system. The Stimulator sends small electrical pulses to the contacts at the end of the DBS Lead, producing stimulation in the brain. The Stimulator is commonly placed underneath the skin in the chest area, below the clavicle. The parameters of the Stimulator will be adjusted by your health care professional after your implantation surgery.

There are also two main external parts to your Vercise™ DBS System:

- The **Remote Control** is a hand-held programmer used to control the Stimulator.
- The **Charging System** is used to periodically recharge the Stimulator.

To make the most of your Vercise DBS System, it is important to learn:

- How to live safely with the Vercise DBS System.
- How to use the Remote Control.
- How to use the Charging System to recharge the Stimulator.

Refer to your *Vercise DBS Charging Handbook* for charging instructions.

***Note:*** *This product contains no detectable latex.*

# Safety Information

## When the Device Should Not be Used (Contraindications)

The Vercise™ DBS System should not be used in cases where patients have the following conditions or will be exposed to the following procedures:

- **Diathermy.** You should not have any form of diathermy either as treatment for a medical condition or as part of a surgical procedure. The energy generated by diathermy can be transferred to the Vercise DBS System, causing tissue damage in the brain, which can result in severe injury or death. The use of shortwave, microwave, and/or therapeutic ultrasound diathermy with the Vercise DBS System implanted may result in severe injury or death.

- **Electroconvulsive therapy (ECT) and transcranial magnetic stimulation (TMS)** The safety of these therapies in patients implanted with the Vercise DBS System has not been established. It is possible that the energy generated by these therapies can be transferred to the Vercise DBS System, causing tissue damage that may result in severe injury or death.

- **Magnetic Resonance Imaging (MRI).**

Patients implanted with the Vercise DBS System should not have an MRI.Patient exposure to MRI can cause (1) dislodgement of implanted components, (2) heating of the contacts or other system components, causing permanent tissue damage, including damage to brain tissue, (3) damage to the device electronics, (4) changes in current flow, causing unpredictable levels of stimulation, (5) distortion of the MRI image, and/or (6) personal injury or death.

- **Patient Incapability.** If you are unable to properly operate the Remote Control and Charging System, then you should not be implanted with the Vercise DBS System.

- **Poor Surgical Candidates.** The Vercise DBS System is not recommended for patients who are poor surgical candidates. Please consult with your doctor to determine your surgical risk.

- **Unsuccessful Test Stimulation**. The Vercise DBS System should not be used in patients who experience unsuccessful test stimulation.

# Warnings

### Unauthorized Modification.

Unauthorized modification to the medical devices is prohibited. System integrity could be compromised and harm or injury to the patient could occur if the medical devices are subjected to unauthorized modification.

### Intracranial Hemorrhage

Placement of the DBS Leads in the brain may increase the risk of intracranial hemorrhages (i.e., bleeding in the brain). If you are more prone to hemorrhage, have trouble forming blood clots (i.e., coagulothapy), or take medication to make your blood thinner, such as aspirin or prescribed anticoagulants, please notify your physician as these may increase your risk of intracranial hemorrhage.

### High Stimulation Levels

High levels of stimulation may damage brain tissue. Your physician will set the maximum and minimum stimulation levels allowed by the Remote Control to ensure that stimulation levels remain safe.

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## Electromagnetic Interference

Strong electromagnetic fields can potentially turn the Stimulator off, cause temporary unpredictable changes in stimulation, or interfere with the Remote Control communication. You should avoid or exercise care around:

- Theft detectors, such as those used at department stores, libraries, and other public establishments. If you must proceed through the detector, you should proceed with caution, ensuring to move through the center of the detector as quickly as possible.
- Security screeners, such as those used in Airport Security or at entrances to government buildings, including hand-held scanners. It is recommended that you request assistance to bypass the screener. If you must proceed through the security screener, proceed with caution, ensuring to move quickly through the security screener and staying as far from the screener as allowable.
- Power lines or power generators.
- Electric steel furnaces and arc welders.
- Large magnetized stereo speakers.
- Strong magnets.
- Automobiles or other motorized vehicles using a LoJack system or other anti-theft system that can broadcast a radio frequency (RF) signal. The high energy fields produced by these systems may interfere with the operation of the Remote Control and its ability to control stimulation.

- Other sources of electromagnetic disturbance, such as RF transmitters at television or radio broadcast stations, Amateur Radio or Citizens Band radio transceivers, or Family Radio Service band transceivers.

*Note: When in close proximity, equipment that generates strong electromagnetic fields might cause unintended stimulation or interfere with wireless communication even if they comply with International Special Committee on Radio Interference (CISPR) requirements.*

### Heat Due to Charging

The Charger may become warm while charging the Stimulator. The Charger should be handled with care. Failure to use either the Charging Collar or an Adhesive Patch while charging, as directed, may result in a burn. You should not charge while sleeping. This may result in a burn. If you experience pain or discomfort, stop charging and contact your physician.

### Suicide

If you notice unusual changes in mood or behavior or have thoughts of suicide, contact your physician immediately.

### Stimulator Damage

Chemical burns may result if the Vercise Stimulator housing is ruptured or pierced and your tissue is exposed to battery chemicals.

## Other Implanted Stimulation Devices

Stimulators, such as the Vercise™ Stimulator, may interfere with the operation of implanted stimulation devices, such as cardiac pacemakers, implantable cardioverter defibrillators, or medication delivery pumps. The effects of implanted stimulation devices on neurostimulators, such as the Vercise DBS System, are unknown.

## Automobiles and Equipment

Operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with caution after receiving the Vercise DBS System. Avoid performing activities that would be dangerous if treated symptoms were to return. Actions that cause stimulation changes to occur should be avoided. Impaired driving performance and an increased accident risk have been previously reported for patients with Parkinson's disease.

If your Vercise™ DBS System ceases treatment for any reason while operating a car, any other motorized vehicle, or potentially dangerous machinery/equipment, you are at an increased risk of causing injury or death to yourself and others.

## Pregnancy

It is unknown whether this device may hurt an unborn baby.

# Precautions

## Other Models of External Devices

Only the Remote Control and Charger that were provided with the Boston Scientific Vercise™ DBS System should be used with the Vercise DBS System. Other similar models of these devices will not function with the Vercise DBS System.

## Stimulator Orientation

Never attempt to change the orientation of or turn over the Stimulator. Avoid touching the Stimulator site or incisions. If the Stimulator flips over in your body, then it cannot be charged. If stimulation cannot be turned on after charging, contact your physician to arrange an evaluation of the system.

If you notice a change in appearance of the skin at the Stimulator location, such as the skin becoming thin over time, contact your physician.

## Device Failure

Implants can fail at any time due to random component failure, loss of battery functionality, DBS Lead breakage, or DBS Lead migration. Suddenly stopping brain stimulation can cause serious reactions to develop. If the Stimulator stops working even after complete charging, turn off stimulation and contact your physician immediately so that the system can be evaluated and appropriate medical care given to manage the return of symptoms.

## Post-Operative

Following your surgery, the medical staff will ensure that you will receive standard medical care:

- A CT Scan may be taken to record the position of the DBS Leads and Stimulator.
- You and a family member will be educated on the system operations, including instructions on how to turn stimulation on and off, how to charge the Stimulator's battery, and realistic expectations of stimulation in the treatment of your disease.
- Antibiotics may be prescribed to prevent infection.
- Post-operative pain concerns will be addressed by your physician prior to discharge from the hospital.

- A responsible adult companion who is able to fully understand the post-operative care instructions will be required to drive you home after the surgery.

During the period following surgery, it is important to use extreme care so that appropriate healing will secure the implanted components and close the surgical incision:

- You should restrict head movements, as instructed by your physician, including extension or flexion of the neck and rotation of the head, until healing is complete.
- Do not attempt to move heavy objects.
- Do not shower until cleared by your physician. Surgical sutures and staples will need to be removed by your physician in a follow-up visit after surgery.
- Follow your physician's instructions regarding how to care for the dressing covering the area where the Stimulator has been implanted.

Initiating your stimulation therapy may be delayed up to two months until swelling (edema) is resolved. The timing will depend on your physician's judgment. If swelling is still present at the Stimulator site (typically in the chest area) once stimulation therapy has begun, swelling may lead to longer charging times or the inability to charge the Stimulator. Post-surgical swelling is expected to subside. If you experience continued swelling, contact your physician.

Temporarily, there may be some pain in the area of the Stimulator until healing is complete. If discomfort continues beyond two weeks, contact your physician.

If you notice excessive redness or drainage around the wound areas, contact your physician. In rare cases, adverse tissue reaction to implanted materials can occur.

### Cell Phones

While interference caused by cell phones is not anticipated, the full effects of interaction with cell phones are unknown at this time. If there is a concern or a problem is encountered, please contact your physician.

### Massage Therapy

You should avoid receiving massage therapy near the implanted system components. If you do receive massage therapy, inform the masseuse that you have an implanted device and show him/her where the Stimulator, DBS Extension, and DBS Leads are located. Have the masseuse avoid these areas and proceed with caution.

### Medical Devices/Therapies

The following medical therapies or procedures may turn stimulation off, cause permanent damage to the Stimulator, and/or may cause you injury, particularly if used in close proximity to the device. If any of the procedures below is required by medical necessity, the procedure(s) should be performed as far from the implanted components as possible. Ultimately,

however, the Stimulator may require explantation as a result of damage to the device or severe injury.

- Electrocautery—The use of a heated electric probe to stop bleeding during surgery
- External Defibrillation—The use of electrically charged paddles to restart the heart in an emergency
- Lithotripsy—High-output sound or shock waves often used to treat gall stones and kidney stones
- Radiation Therapy—Ionizing energy commonly used to treat cancer. Any damage to the device by radiation may not be immediately detectable.
- X-ray and CT scans may damage the Stimulator if stimulation is on. X-Ray and CT Scans are unlikely to damage the Stimulator if stimulation is turned off.

Diagnostic ultrasonic scanning is unlikely to damage the Stimulator if stimulation is turned off.

Before having these procedures, medical therapies, or diagnostics, have your healthcare professional call the Boston Scientific Technical Support department for proper instructions.

## Component Disposal

Any explanted components should be returned to Boston Scientific. The Stimulator should be explanted in the case of cremation and returned to Boston Scientific. Cremation may cause the Stimulator battery to explode.

The Remote Control or Charging System should not be disposed of in fire. These components contain batteries, which may explode causing injury when exposed to fire. Used batteries should be disposed of in accordance with local laws and regulations.

## Storage, Handling and Transport

Do not expose the Remote Control or Charging System components to excessively hot or cold conditions. Do not leave the devices in your car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat. For proper operation, do not use the Charger if the ambient temperature is above 35° C (95° F).

If the Remote Control or the Charging System is to be stored for a period of time, be careful that the storage temperature

does not exceed -20–60° C (-4–140° F).

Handle the system components and accessories with care. Do not drop them or submerge them in water. Accessories, including the Remote Control, Charger, and charging components must be kept dry and not be exposed to moisture. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components. Keep the Remote Control, Charger, and charging components away from pets, pests, and children to avoid damage to the devices.

### Remote Control and Charging System Cleaning

The external components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Residue from soapy detergents should be removed with a damp cloth. Do not use abrasive cleansers for cleaning. Remove the Charger and Counterweight from the Charging Collar before washing the Charging Collar. Wash the Charging Collar with mild soap and warm water. Do not machine wash the Charging Collar. Let the Charging Collar air dry. Do not use the Charging Collar when it is damp or wet. Do not clean the Charger, Base Station, or Power Supply while they are directly or indirectly connected to a power outlet.

As an operator of the external devices, you should perform only the following service and maintenance tasks on the external devices:

- Charging the battery
- Cleaning

Ensure that the devices are not in use while performing service and maintenance tasks.

## Adverse Events

The following is a list of known risks with the use of Deep Brain Stimulation for treatment of Parkinson's disease. It is possible there are risks that are unknown. Note that some of these symptoms may be resolved or reduced by current steering, changing stimulation parameters or by changing the position of the DBS Lead during surgery.

If any of these events occur, you should contact your physician as soon as possible to inform them.

## Risks associated with Surgical Procedure and Post-operative period

- Allergic reaction to anesthesia or antibiotics including anaphylaxis
- Blood clot formation in the extremities (e.g., in the veins of the legs)
- Blood clot or air forming in or traveling through the blood stream, which can block blood flow to parts of the lungs or other tissue that could be life-threatening.
- Brain contusion (bruising)
- Brain or cerebspinal fluid infection or inflammation
- Cerebral spinal fluid (CSF) leaking outside the skull or collecting inside the skull abnormally.
- Confusion or problems with attention, thinking, or memory (acute or chronic)
- Death
- Fibrosis (thickened skin and scarring) around the lead extension (including tightening, tethering, and bowstringing)
- Hemiparesis (muscular weakness or partial paralysis on one side of the body)
- Hemiballism (uncontrollable involuntary movements of a limb or limbs on one or both sides of the body))
- Intracranial hemorrhage (which can lead to stroke, paralysis, or death)
- Intraparenchymal cyst
- Infection
- Injury to areas next to the implant, such as blood vessels, nerves, the chest wall, and the brain
- Injury to the nerves in the armpit (brachial plexus) leading to pain or weakness of the arm or hand
- Neurosurgery/anesthesia risks, including unsuccessful implant and pneumonia
- Pain at the surgical site(s), headache or discomfort

- Seizures
- Speech or language difficulties
- Subcutaneous hemorrhage or seroma (blood or fluid colletion under the skin, including the skin over the skull).
- Stroke resulting in temporary or permanent problems
- Swelling or bruising of the muscles or skin in the area of the lead or of the IPG implant

## Possible Side-Effects of Stimulation

- Confusion or problems with attention, thinking, or memory
- Gait difficulty (trouble walking) and falls
- Pain, headache or discomfort
- Pneumonia from difficulty with swallowing or from inhaling fluid
- Psychiatric disturbances such as anxiety, depression, lessened interest or emotion, hypersexuality, aggression, mania or hypomania, pyschosis, emotional sensitivity, sleep problems, suicide, or suicidal thoughts or attempts
- Seizures
- Sensory changes
- Speech or language problems
- Swallowing difficulty
- Systemic effects such as rapid heart beat, sweating, fever, dizziness, changes in kidney function, difficulty passing urine, sexual effects, nausea, difficulty having bowel movements, bloating
- Weakness, muscle spasms, shaking, restlessness, or problems with movement,
- Undesirable sensations (e.g., tingling)
- Visual problems, eyelid or eye movement difficulties or other eye-related symptoms
- Weight changes

## Device-related Risks

- Allergic or immune system response to implanted materials
- Failure or malfunction of any part of the device, including but not limited to: Battery leakage, battery failure, lead or extension breakage, hardware malfunctions, loose connections, electrical shorts or open circuits, and lead insulation breaches, whether or not these problems require device removal and/or replacement
- Implant site complications such as pain, poor healing, redness, warmth, swelling or wound reopening
- Implanted device components (stimulator, lead, or extension) may move from original implanted location or wear through the skin, which may lead to the need for additional surgery
- Infection
- Interference from external electromagnetic sources
- Loss of adequate stimulation
- Pain, headache or discomfort.
- Skin irritation or burns at the stimulator site
- Stiffness in muscles or joints
- Worsening of disease symptoms, potentially caused by loss of stimulation, medication changes, surgery, or illness. In rare cases worsening can become a life-threatening crisis associated with varied symptoms such as mental status changes, fever, and muscle rigidity
- Swelling, including fluid collecting around the device

# Getting Set Up

Check that you have received all of the following items before reading more about the Vercise ™ DBS System:

1. Charging Collar (2)
2. Adhesive Patches (52)
3. Base Station (1)
4. Power Supply (1)
5. Counterweight (1)
6. Remote Control Case (1)
7. Remote Control Batteries (3)
8. Remote Control (1)
9. Charger (1)
10. Charging Spacer (1)

Refer to your Vercise DBS Charging Handbook for charging instructions.

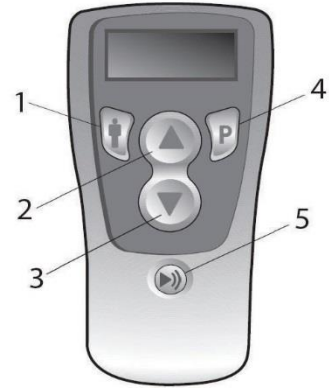
# Using the Remote Control

The Remote Control unit is your direct link to check the battery level of your stimulator and turn your stimulation on and off. *Keep the Remote Control with you at all times.* It is important to be able to turn stimulation back on as soon as possible if it is accidentally turned off (for example, by walking through a theft detector). This section describes how to use the Remote Control functions to optimize your therapy.

**Note:** *Your physician may also give you the ability to change your stimulation level with your Remote Control.*

To use most Remote Control functions, you will simply press a button as you would on a TV remote control. Some functions require you to press and hold a button until the desired action occurs (about three seconds). To best view the Remote Control screen, tilt the screen away from direct light sources.

***Note:*** *The operating temperature range for the Remote Control is 5 to 40 °C (41 to 104 °F).*




1. Area Button
2. Up/Activate
3. Down/Save
4. Program Button
5. Stimulation On/Off

# Inserting the Remote Control Batteries

1 On the rear of the Remote Control, push the battery compartment cover in slightly and slide down the cover.

2 Remove the old batteries.

3 Place three new AAA batteries in the slots, matching the positive (+) and negative (-) markings in the compartment.

4 Align the battery compartment cover on the case and slide the cover into position until it snaps closed.

The Remote Control will connect to the Stimulator in approximately 30 seconds.

***Note:*** *If your Stimulator will be off for an extended period of time, it is recommended that you remove the batteries from the Remote Control.*

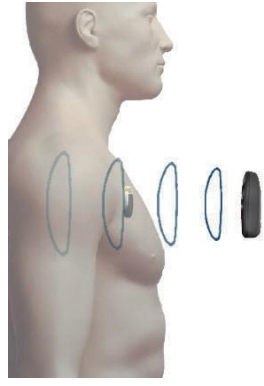
## Remote Control Battery Life

The Remote Control uses three AAA batteries. Under typical usage, the Remote Control batteries will last 15 days before replacement is necessary.

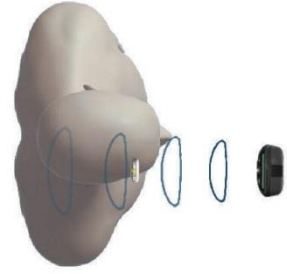
# Positioning the Remote Control

You will achieve a strong communication link between the Remote Control and the implanted Stimulator if the Remote Control is positioned as shown in the pictures below.

**Side View**



**Top View**



In some situations, you may need to bring the Remote Control closer to the Stimulator. The distance at which you will be able to achieve communication depends on your environment and the relative orientation of the Remote Control to the implanted Stimulator.

# Waking Up and Unlocking the Remote Control

When it is not being used, the Remote Control automatically enters sleep mode and the display screen is blank. To prevent accidental use, there is a safety feature that locks the Remote Control's buttons in sleep mode (except for the ▶)) button).

**English Screen***

**Iconic Screen***

To wake up and unlock the Remote Control:

1 Press any button on the Remote Control (except the ▶)) button). It will wake up and display the screen shown on the right.

***Note:*** *The normal function of the particular button that is pressed will not be performed. Pressing ▶)), however, at any time—even while the Remote Control is in sleep mode – will turn stimulation on or off.*

2 Press and hold **P**. While the **P** button is held down, the circles will fill one by one until all circles are filled.

3 When the “Release **P** To Unlock” message appears, release the **P** button. The Remote Control will immediately look for your Stimulator and then connect to it, allowing you to make adjustments to your stimulation.

If the Remote Control is not used (no buttons are being pressed) for at least a minute, it will automatically enter sleep mode and the buttons will lock.

*Note: The Remote Control screen images in this manual include an English version (top) and an Iconic version (bottom)*

# Communicating with the Stimulator

Good communication between your Stimulator and the Remote Control is very important. For that reason, you will sometimes see the following icon on your screen. This indicates that the Remote Control is checking for the Stimulator.

***Note:*** *If there is a problem communicating with the Stimulator, the message "No Response" will appear on the Remote Control screen. Press* **P** *to retry, or press* 🧍 *to cancel.*

The table below explains the meaning of the action icons that are displayed on various Remote Control screens, including the No Response screen that is described above.

| Graphic | Description |
|---|---|
| | Retry the Action. |
| | Accept / Perform the Action / Yes |
| | Cancel / Abort the Action / Return to the Previous Screen / No |

# Turning Stimulation On and Off

The Remote Control uses a dedicated stimulation on/off button.

To turn stimulation on or off:

1 Press ▶)) at any time—even while the Remote Control is in sleep mode.

The Remote Control will briefly display a message notifying you of the on or off status.

## Checking Stimulation Status

Stimulation is on when the remote control displays

.
You can verify the status of your stimulation (ON/OFF) using the following steps:

1 Press ▶)) at any time – even while the Remote Control is in sleep mode. Pressing this button will change the stimulation status.

2 After pressing ▶)):

a If the remote control displays

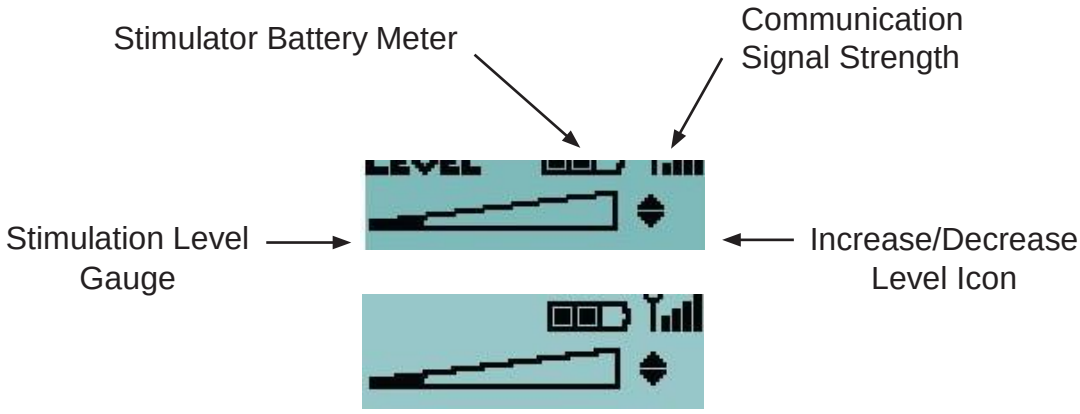
, your stimulation was previously OFF.

b If the remote control displays

, your stimulation was previously ON. Press ▶)) again to turn the stimulation ON.

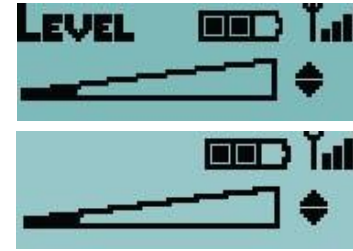
## Understanding the Level Screen

After the Remote Control is unlocked, or whenever stimulation is turned on, the Remote Control will display the Level screen. The Level screen displays the stimulation level gauge, the Stimulator battery meter, the communication signal strength between the Stimulator and Remote Control, and the increase and decrease stimulation level icon.



# Identifying the Communication Signal Strength

The Remote Control indicates the strength of the communication signal between itself and the Stimulator in the upper right corner of the display, similar to a mobile phone.




You will achieve a strong communication link between the Remote Control and the implanted Stimulator if the Remote Control is positioned as shown in *Positioning the Remote Control*.

| Communication Signal Strength | Description |
|---|---|
| | The Remote Control is achieving *optimal* communication with your Stimulator. |
| | The Remote Control is achieving *good* communication with your Stimulator. |

| Communication Signal Strength | Description |
|---|---|
| | The Remote Control is achieving *OK* communication with your Stimulator. |
| | The Remote Control is achieving *weak* communication with your Stimulator. |
|  | The Remote Control is achieving either *very weak* or *no* communication with your Stimulator.<br><br>Communication between the Remote Control and the Stimulator may or may not be achieved. To improve the communication speed, move the Remote Control closer to the Stimulator and position it as shown in *Positioning the Remote Control*. |

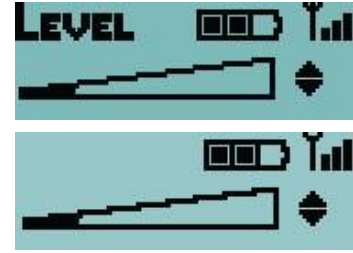
When the communication signal strength between the Stimulator and Remote Control is very weak, the “Searching” message will be displayed. The Remote Control is attempting to communicate with the Stimulator. To establish a stronger communication signal strength, move the Remote Control to a better position (refer to *Positioning the Remote Control*).

To cancel searching, press .

***Note:*** *Avoid common sources of interference, such as televisions and computer monitors when trying to use the Remote Control.*

## Understanding the Stimulator Battery Meter

The Level screen displays a battery meter near the top center to indicate the Battery Charge Level of your Stimulator.




***Note:*** *This is the battery level of your Stimulator, not your Remote Control.*

Three filled-in bars means that the Stimulator has a fully-charged battery. As the battery strength wears down, depending on your stimulation settings and usage, the bars will empty accordingly.

| Battery Meter | Description |
|---|---|
| | The Stimulator's battery is *full*. |
| | The Stimulator's battery is *ok*. |
| | The Stimulator's battery is *low*. |

For complete information on maintaining your Stimulator's battery, see your *Vercise DBS Charging Handbook*.

The Remote Control unit is your direct link to check the battery level of your stimulator. *Keep the Remote Control with you at all times.*

***Note:*** *Remember, the Level screen will remain on the display for approximately one minute if you do not press a button to perform an action with the Remote Control. After a minute, the Remote Control enters sleep mode and the display will go blank.*

# Selecting and Activating a Program

A stimulation program is a set of stimulation parameters that determine your therapy. A program may apply stimulation to up to four independent stimulation fields or areas, depending on how the program is set up by your physician.

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 you to select and activate at any time. Your physician may decide to give you one program or multiple programs.

The following chart describes the different graphics you may see at the top of the Program screen.

| Program Graphic | Description |
|---|---|
| | An empty program slot |
| | A program is saved in the program slot |
| | The most recently activated or saved program |

| Program Graphic | Description |
|---|---|
| 1 | The currently selected program slot |
| P | A reminder that the **P** button changes the selected program |

***Note:*** *All four of the Remote Control's program slots may not contain a saved program. If you try to activate an empty program slot, nothing will happen.*

To select and activate a program:

1 Press the **P** button from the Level screen to go to the Program screen.

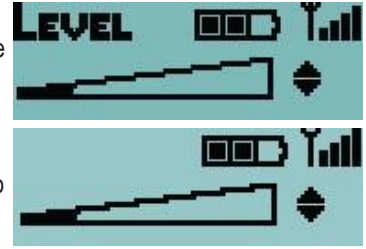
2 Press **P** or ▲ to move until the program you want is selected (indicated by the solid box).

| | |
|---|---|
| Pressing **P** will select the next program | |
| Pressing will select the previous program | |

***Note:*** *Pressing* **P** *from program 4 returns you to the Level screen.*
*Pressing* *from program 1 also returns you to the Level screen.*

3 Press ▲ to activate the program. The Remote Control will return to the Level screen.

# Changing the Stimulation Level of a Program




Usually, changes to the level of stimulation will not be permitted using the Remote Control. In these cases, your physician will determine the optimal level for your stimulation therapy. However, for certain patients, physicians may allow patients to change stimulation levels.

If your physician has allowed you to control your stimulation level, use the ▲ or ▼ to adjust the level of stimulation for the activated program:

- Press the ▲ button to increase the level of your stimulation. The stimulation level gauge will fill as the stimulation level increases.
- Press the ▼ button to decrease the level of your stimulation. The stimulation level gauge will empty as the stimulation level decreases.

If you are allowed to control your stimulation level, you will be given a limited range within which you can adjust the stimulation level. The increase/decrease level icon indicates when you can increase and decrease the stimulation level, as shown in the chart below.

| Increase/Decrease Level Icon | Description |
|---|---|
| | You can increase or decrease the stimulation level. |
| | You have reached the minimum stimulation level. You can only increase the stimulation level. |
| | You have reached the maximum stimulation level. You can only decrease the stimulation level. |

When you reach the maximum or minimum stimulation level allowed by your physician, the Remote Control will beep.

***Note:*** *Your physician may set your default stimulation level outside of your therapeutic range. If you decide to adjust your stimulation level into your therapeutic range, you will not be able to return to the default stimulation level using the ▲ and ▼ buttons. To return to your default stimulation level, use the Restore function (see* Restore an Original Program*).*

***Note:*** *Remember, the Level screen will remain on the display for approximately one minute if you do not press a button to perform an action with the Remote Control. After a minute, the Remote Control will enter sleep mode and the display will go blank.*

## Changing the Stimulation Level of an Individual Area

For certain patients, physicians may allow patients to change the stimulation levels of individual areas of a program. A program may apply stimulation to up to four independent stimulation fields or areas, depending on how the program is set up by your physician.

To adjust the stimulation level of an individual area:

1 Press the button as needed from the Level Screen to cycle to a specific stimulation area.

2 Press the ▲ button to increase the stimulation level of the selected area or the ▼ button to decrease the stimulation level of the selected area.

## Saving Changes to Your Stimulation Level

If your physician has allowed you to change your stimulation level, you may choose to save any changes you make to the stimulation level. Saving changes to your stimulation level permanently changes the stimulation level of the program.

***Note:*** *If you are not permitted to change your stimulation level, please disregard this section.*

To save your stimulation level changes:

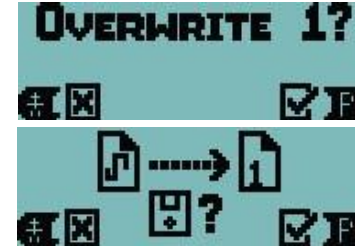
1 Press **P** from the Level Screen to go to the Program screen.

2 From the Program screen, press **P** as many times as necessary to select the program slot in which you want to save the program with your new stimulation level.

| | |
|---|---|
| To update the active program with your new stimulation level, select the active program (indicated by the underlined box). | |
| To save changes as a completely new program (if an empty program slot is available), select the empty program slot (indicated by the empty box). | |

3 Press ▼ to save the change in the selected program slot in the Remote Control's memory.

4 The Remote Control will ask you to confirm that you want to overwrite the selected program. Press P to confirm the change or press to cancel the saving process.



# Restore an Original Program

If your physician has allowed you to change your stimulation level, you may have made changes to the stimulation level of one or more of the programs originally saved to your Remote Control by your physician. The Restore function allows you to return to the original stimulation level if you ever become dissatisfied with a changed program.

1 From the Level Screen, press and hold **P** to reach the Restore screen. Program 1 will be selected (indicated by the solid box).

***Note:*** *Make sure you see the word "Restore" on the screen before proceeding.*

2 If necessary, press **P** to cycle through the program slots until the program you want to restore is selected.

***Note:*** *Pressing* 🧍 *from program 1 will return you to the Level Screen.*

3 When the desired program is selected, press ▲ to restore the selected program. The Remote Control will briefly flash a message confirming the restoration.

## Understanding Battery Messages

It is critical that you keep your Stimulator battery charged to allow you to maintain consistent therapy and avoid uncontrolled return of your Parkinson's disease symptoms. Your current medication dose may not be adequate to control your symptoms safely without stimulation. The rechargeable battery in your Stimulator and the replaceable batteries in your Remote Control provide you with dependable treatment. Always pay close attention to the battery messages described in this section.

| Battery Message | What to do |
|---|---|
| | 1 Press the **P** button.<br>2 Replace the Remote Control batteries, as described in *Inserting the Remote Control Batteries*. |
| | 1 Press the **P** button.<br>2 Replace the Remote Control batteries, as described in *Inserting the Remote Control Batteries*. |
| | 1 Press the **P** button.<br>2 Recharge the Stimulator as soon as possible, as described in *Vercise DBS Charging Handbook.* |
| | 1 Press the **P** button.<br>2 Recharge the Stimulator as soon as possible, as described in your *Vercise DBS Charging Handbook*. |

## Remote Control Battery Messages

When the Remote Control batteries are at a low power level, the "Remote Battery Low" battery message will be displayed. Do not ignore the message to replace the batteries.

When you see this message:

1 Press the **P** button.

2 Replace the Remote Control batteries, as described in *Inserting the Remote Control Batteries*

***Note:*** *Make a habit of replacing the Remote Control batteries when you first see the "Remote Battery Low" message.*

If you don't respond to the "Remote Battery Low" message in a timely manner, the batteries will eventually drain to the point of not having enough power to manage your Stimulator. At this point, you would see the more urgent message, "Replace Remote Battery." You must respond immediately!

When you see this message:

1 Press the **P** button.

2 Replace the Remote Control batteries as described in *Inserting the Remote Control Batteries*.

## Stimulator Battery Messages

When your Stimulator battery is getting low, the Remote Control will display the “Recharge Stimulator Soon” battery message.

When you see this message:

1 Press the **P** button.

2 Recharge the Stimulator as soon as possible, as described in *your Vercise DBS Charging Handbook*.

***Note:*** *Make a habit of charging the Stimulator when you first see the “Recharge Stimulator Soon” message.*

If the Stimulator is not recharged and the Stimulator's battery becomes very low, the Remote Control will display a "Recharge Stimulator Now" message.

When you see this message:

1 Press the **P** button.

2 Recharge the Stimulator immediately, as described in your *Vercise DBS Charging Handbook*.

**CAUTION:** If you do not charge your Stimulator immediately, it will enter Hibernation Mode within less than 24 hours and stimulation will automatically turn off. When the Stimulator is in Hibernation Mode, stimulation will turn off and it cannot be restored until the Stimulator has been charged. Recharge the Stimulator (possibly for several hours) to exit Hibernation Mode. See your *Vercise DBS Charging Handbook*.

***Note:*** *The Remote Control will continue to display the "Recharge Stimulator Now" message until the Stimulator is recharged.*

***Note:*** *If you are having trouble turning on stimulation after fully recharging the Stimulator, please contact your physician.*

# About the Vercise™ Stimulator

The Vercise Stimulator is rechargeable. You should expect a daily recharging time of 15 to 30 minutes or a periodic recharging time of 3 to 4 hours every 1 to 2 weeks, but your recharge routine may vary depending on your stimulation parameters. High power users will require more frequent charging. Boston Scientific recommends any recharge routine that fits your schedule and lifestyle while maintaining sufficient charge to maintain stimulation.

***Note:*** *Do not worry that variations in your charging routine will affect or diminish the battery life of the Stimulator.*

Developing a recharge routine involves finding the right balance between four factors:

- How much power is required to experience effective therapy.
- How often you want to recharge.
- How long you want to recharge.
- How you would like to manage your personal schedule.

The Vercise DBS System's programming software gives your physician a conservative recommendation for how often to charge. This estimate assumes stimulation is on 24 hours per day, 7 days a week at the default stimulation level. While you may want to follow these recommendations, you and your physician can also develop an appropriate charge routine that best fits your schedule.

Keep in mind, if you do not charge your Stimulator before it enters Hibernation Mode, stimulation will stop until you charge the Stimulator again. Developing a charging routine you are comfortable with will help prevent you from losing stimulation due to a low battery.

The Remote Control provides an easy-view Stimulator battery meter on the Level screen as well as messages to inform you of the battery's condition. These messages are explained in *Understanding Battery Messages*.

After years of service, the Stimulator may require shorter intervals between charges. For example, a Stimulator with settings requiring charging every 22 days during the first year is expected to require charging every 20 days after five years
of continuous use.* The Stimulator will need replacement when stimulation can no longer be maintained with routine charging.

* Calculated using a single area with the following stimulation parameters: amplitude = 3 mA, pulse width = 60 μsec, rate = 185 Hz, and impedance = 1500 Ohms.

# Troubleshooting

## Remote Control Warning Messages

### “Recharge Stimulator Now”

Stimulation has stopped if you see this message. You will probably need to recharge your Stimulator for several hours before stimulation can be turned on.

### “Replace Remote Battery”

The batteries in your Remote Control need to be replaced with three fresh AAA batteries (see *Inserting the Remote Control Batteries*).

## “No Response”

There is a communication problem between the Remote Control and the Stimulator, probably caused by a weak Stimulator battery.

1 Properly position the Remote Control (see *Positioning the Remote Control*).

2 Press the **P** button to retry the action or press **T** to cancel.

If the Remote Control connects with your Stimulator, you will be returned to the display you were using before the problem began. If your attempts to reconnect fail several times, recharge the Stimulator and check to see if the problem is solved.

Occasionally, communication problems happen because the Remote Control cannot find the Stimulator because of orientation or interference. Move the Remote closer to your Stimulator and then press the **P** button. If the problem continues, please contact the Boston Scientific Technical Support department for your locality.

# Error Messages

If the Remote Control displays the following error screens:

1. Make a note of the numbers (the error code) on the screen.
2. Move the Remote Control closer to your Stimulator and position it as shown in *Positioning the Remote Control*. Since most error codes you might encounter are related to communication, always try to resolve the prob lem by properly positioning the Remote Control and/or moving it closer to your Stimulator.
3. Press **P** and wait a few seconds.
4. Try the action again.
5. If the error code is still displayed, please contact the Boston Scientific Technical Support department.

***Note:*** *The Remote Control will enter sleep mode when* **P** *is pressed or within approximately fifteen seconds if* **P** *is not pressed.*

## Technical Support

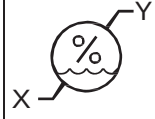
There are no user serviceable parts. If you have a specific question or issue, please contact your healthcare professional. If you need to contact Boston Scientific for any other reason, please call (833) DBS-INFO or (833) 327-4636.

# Labeling Symbols

The symbols used in the labeling of the Vercise™ system internal and external components are as follows:

| | |
|---|---|
| ℞ ONLY Prescription only | 20XX-XX Use by YYYY-MM |
| REF Model Number | Y° C / X° C Temperature product should be stored at |
| SN Serial Number | Consult the Instructions for Use |
| 20XX-XX Date of manufacture | Fragile |

| | |
|---|---|
| AUS Australian Sponsor Address | EC REP EU Authorised Representative |
| STERILE EO Ethylene Oxide sterilized | Single use only |
| NON STERILE Non-Sterile | Do not resterilize |
| Type of Protection: BF | Caution, consult accompanying documents |
| Double Insulation | WEEE Directive |

| | |
|---|---|
| Contents | Batch Code |
| Do not use if package is damaged | Refer to instruction manual/booklet |
| Legal Manufacturer |   Humidity Limitations |
| Keep Dry | MR Unsafe |

# Electromagnetic Compatibility

## EN 60601-1-2 Classification Information

- Internally Powered Equipment
- Continuous Operation
- Ordinary Equipment
- Class II

**Guidance and manufacturer's declaration – electromagnetic emissions**

| The Vercise DBS System is intended for use in electromagnetic environment specified below. The customer or the user of the Vercise DBS System should ensure that it is used in such an environment. | | |
|---|---|---|
| **Emissions Test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions CISPR 11 | Group 1 | The Vercise DBS System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The Vercise DBS System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class B | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
|---|---|---|---|
| The Vercise DBS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Vercise DBS System should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | Air: ±2kV, ± 4kV, ± 8kV, ±15kV<br>Contact:±8kV | Air: ±2kV, ± 4kV, ± 8kV, ±15kV<br>Contact:±8kV | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %<br>**Note:** Applies to external devices. |
| Electrical fast transient/ burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/ output lines | N/A – system is not connected to supply mains | N/A – system is not connected to supply mains |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | N/A – system is not connected to supply mains | N/A – system is not connected to supply mains |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0,5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$)<br>for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 5 s | N/A – system is not connected to supply mains<br><br>T<br><br>T<br><br>T<br><br>T<br><br>T<br><br>T | N/A – system is not connected to supply mains |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Magnetic fields from common appliances are not expected to affect the device. |
| | | | |

**Guidance and manufacturer's declaration – electromagnetic immunity**

The Vercise DBS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Vercise DBS System should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - guidance |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 (ETS only) | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz | Professional healthcare facility environment and home healthcare environment |
| Radiated RF IEC 61000-4-3 | 10 V/m, 80 MHz to 2.7 GHz | 10 V/m, 80 MHz to 2.7 GHz | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol shown below: |

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Vercise DBS System is used exceeds the applicable RF compliance level above, the Vercise DBS System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Vercise DBS System.

| Recommended separation distances between portable and mobile RF communications equipment and the Vercise DBS System |
|---|
| The Vercise DBS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Vercise DBS System can help prevent electromagnetic interference by maintaining a minimum distance of 30 cm between portable and mobile RF communications equipment (transmitters) and the Vercise DBS System. |
| NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |

## Essential Performance

Failure of the external electrical components will not result in an unacceptable risk to the user.

### Quality of Wireless Service

The Vercise System uses a Half-Duplex, direct point-to-point, primary-secondary communication system with the following characteristics:

- **Typical range:**
  - » 18 inches (45 cm) between Remote Control and Stimulator.
- **Timing**: Once a command is initiated by the user, the system will respond in less than 1.5 seconds.
- **Telemetry failures**:
  - » The signal to noise ratio is measured before initiating a communication. Telemetry failures can occur if signal-to-noise ratio is low. Signal to noise measurement is retried up to three times in case of insufficient range or in the presence of electromagnetic disturbances. User is notified of the communication failure after 3 failed attempts.
  - » Packet and message errors are verified for accuracy. Any erroneous packets/ messages are rejected and

re-sent up to 3 times. User is notified of the communication failure after 3 failed attempts.
» User may re-try the command or follow on-screen instructions for telemetry help.

### Wireless Security

The Vercise System has a short range inductively coupled telemetry system.
A Remote Control has to be linked with a stimulator to allow communication.
The Stimulator will not respond to any device that it is not linked to. There are additional mechanisms that ensure the integrity of the communicated data.

### Telemetry Information

The following parameters describe the wireless communication link between the Stimulator and the Remote Control

- Frequency Band: 119 – 131 kHz
- Modulation type: FSK
- Effective Radiated Power: 0.4 mW (-4 dBm) maximum
- Magnetic Field Strength (at 3 m distance): 94 µA/m

## FCC Compliance

The following is federal government communications regulation information about the Vercise™ DBS System.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

The Vercise DBS System components should only be serviced by Boston Scientific. Do not attempt to open or repair any of the components.

Changes or modifications to this product not authorized by Boston Scientific Corporation could void the FCC Certification and negate your authority to operate this product.

Boston Scientific

Advancing science for life™

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Boston Scientific

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# Vercise™ DBS Charging 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.

## Trademarks

All trademarks are the property of their respective holders.

## 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

Refer to the *Vercise DBS System Patient Manual,* for additional instructions and information about your DBS system.

## Product Model Numbers

| Model Number | Product Name |
|---|---|
| DB-64125-US | Vercise Charging System |
| DB-6300-C | Vercise Charging Collar Accessories |
| DB-6200-C | Vercise Charging Collar, Small |
| DB-6100-C | Vercise Charging Collar, Medium |
| NM-6350 | Adhesive Kit |
| NM-5312 | Charger |
| NM-5305 | Base Station |
| SC-6300 and NM-6300 | Power Supply for Charger (US) |

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# Introduction

The Boston Scientific DBS System is used for deep brain stimulation (DBS), a reversible therapy where structures in the brain are stimulated with small electrical pulses. The Boston Scientific DBS System includes a rechargeable stimulator that will require periodic recharging.

The Charging System allows you to recharge the Stimulator battery as needed. The Charging System for the Stimulator consists of the Charger, a Base Station, and a Power Supply. The Base Station is designed to remain connected to a power outlet at all times. When it is not being used, keep the Charger on the Base Station so that it is always ready to deliver a charge.

This manual provides you with instructions for charging your stimulator. We encourage you to read this and your other Boston Scientific manuals entirely. If you have any questions, or need clarification on anything contained in this manual, please contact Boston Scientific.

# Using the Charging System

The Boston Scientific Stimulator is rechargeable. You should expect a daily recharging time of 15 to 30 minutes or a periodic recharging time of 3 to 4 hours every 1 to 2 weeks. Your recharge routine may vary depending on your stimulation parameters. High power users will require more frequent charging. Boston Scientific recommends any recharge routine that fits your schedule and lifestyle while maintaining sufficient charge to maintain stimulation.

Developing a recharge routine involves finding the right balance between four factors:

- How much power is required to experience effective therapy.
- How often you want to recharge.
- How long you want to recharge.
- How you would like to manage your personal schedule.

The Boston Scientific DBS System's programming software gives your healthcare provider a conservative recommendation for how often to charge. This estimate assumes stimulation is on 24 hours per day, 7 days a week at the programmed energy output level. While you may want to follow these recommendations, you and your physician can also develop an appropriate charge routine that best fits your schedule.

The Remote Control provides an easy-view Stimulator battery meter on the Home screen as well as messages to inform you of the battery's condition. When the Remote Control indicates a low battery the Stimulator should be recharged as soon as possible. Failure to recharge may lead to loss of stimulation. After stimulation stops, communication with the Stimulator will also cease until a sufficient level of charge has been attained. Refer either to your *Vercise DBS Patient Manual* or your Remote Control Handbook for more information.

The life of the Stimulator battery is dependent on the stimulation settings and conditions. Over time and with repeated charging, the battery in the Stimulator will lose its ability to recover its full capacity. As a result, over time, the Stimulator may require shorter intervals between charges. The Stimulator will need replacement when stimulation can no longer be maintained with routine charging.

# Getting Set Up

Check that you have received all the components below, which are included in your DB-64125-US Vercise Charging System. If any item is missing, please call the Boston Scientific Customer Service department for a replacement.

1. Charging Collar (2)
2. Base Station (1)
3. Power Supply (1) and Adapters
4. Counterweight (1)
5. Charger (1)
6. Charging Spacer (1)

Also, be sure you received your Patient Identification Card from your physician.

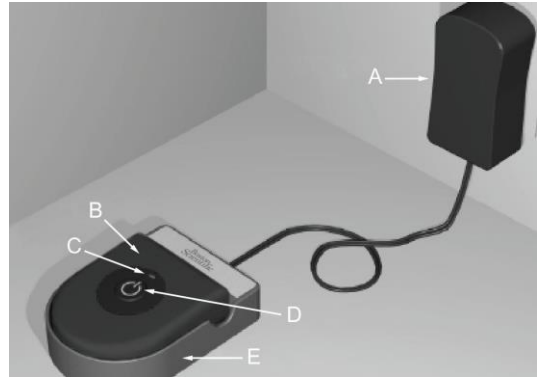
# Charging the Charger

The Charger contains a rechargeable battery that is used to recharge your Stimulator's battery.

**Cautions:**

- Keep the Charging System dry. It should not be exposed to moisture.
- Do not connect the charger to any other device except to the Base Station provided with it.
- Keep the Charging System away from pets, pests and children to avoid damage to the device.

To charge the Charger:




A. Power Supply
B. Charger
C. Indicator Light
D. Power Button
E. Base Station

1. Find a convenient electrical outlet that meets the following criteria:
   - will not expose the Charging System to water or direct heat
   - next to a flat, clear surface for the Base Station.
2. Plug the Power Supply into a standard AC wall outlet.
3. Connect the Power Supply to the Base Station.
4. Place the Charger in the Base Station with the power button facing up.

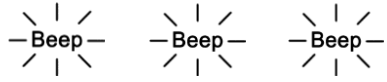
The Charger is ready to fully charge your Stimulator when the indicator light is green. If the light is yellow, the Charger can only partially charge the Stimulator. It may be used, but it may not be able to return your Stimulator to a full charge (and you may need to charge sooner than usual).

| Indicator Light | Description |
|---|---|
| Green | The Charger is fully charged and ready to charge the Stimulator. |
| Yellow | The Charger is partially charged. The Charger may still be used, but it may not be able to fully charge the Stimulator. To fully charge the Charger, place it in the Base Station. |
| Off | The Charger is off –or– the Charger battery is empty. If pressing the Power Button does not turn on the Charger, place the Charger in the Base Station to charge. |

**Charger Battery Service Life**: The Charger battery has a typical service life of 500 charging cycles.

# Understanding the Charger Sound Alerts

The Charger emits different sounds to alert you of specific situations. Before you begin charging your Stimulator, it is important to understand these sounds. The following chart describes what each sound means.

| Sound | Description | |
|---|---|---|
|  | Repeated Single Beep | The Charger is searching for your Stimulator and is not properly aligned with the Stimulator. Align the Charger as shown in the section *Properly Aligning the Charger*. |
| | Repeated Double Beep | The Charger has fully charged the Stimulator battery. Turn off the Charger and return it to the Base Station. |

# Charging Your Stimulator

When charging, you must use the Charger with either the Charging Collar or an Adhesive Patch to hold the Charger over the Stimulator. The Adhesive Patches are made of non-reactive and natural Latex-free material suitable for most sensitive skin types.

⚠ **WARNINGS:**

- Do not charge while sleeping. This may result in a burn.
- While charging, the Charger may become warm. It should be handled with care.
- Failure to use either the Charging Collar or an Adhesive Patch while charging may result in a burn. If pain or discomfort is felt, cease charging and contact your physician.

# Using the Charging Collar

1 When the indicator light is green, remove the Charger from the Base Station. (The indicator light will go off, regardless of the ready status of the Charger.)

2 If instructed to do so by your physician, place the Charging Spacer at the back of the pocket.

3 Place the Charger into the appropriate pocket on the Charging Collar with the power button facing out, as shown. If your Stimulator is on the right side of your chest, place the Charger in the right pocket. If the Stimulator is on the left side of your chest, place the Charger in the left pocket.

4 If instructed to use the Charging Spacer, make sure it is between the Charger and the back of the pocket.

5 Place the Counterweight in the pocket opposite of the Charger.

6 Put the Charging Collar over your neck, with the pockets facing out, as shown.

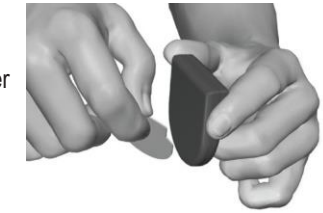
7 For best charging results, make sure the Charger is centered over the Stimulator. If the Charger is not centered, charging time may increase. See sections *Properly Aligning the Charger* and *Tips for Properly Aligning the Charger* to ensure you center the Charger over the Stimulator. It is recommended that you follow the instructions in both sections the first time you charge your Stimulator.

8 If the Charger is not centered over the Stimulator, you may need to adjust the length of the Charging Collar using the straps. Occasionally checking that the Charger is aligned over the Stimulator during your charging session is recommended.

***Note:*** *The Charging Collar can be placed under or over clothing. You should not wear tight fitting or heavy clothing over the Charger while charging to allow air flow around the Charger.*

***Note:*** *Do not use the Charging Collar when it is wet or damp.*

# Using the Adhesive Patch



1 When the indicator light is green, remove the Charger from the Base Station. (The indicator light will go off, regardless of the ready status of the Charger.)

2 Apply the Adhesive Patch to the backside of the Charger by peeling the clear liner from the patch and applying the white side with the blue stripe to the rear of the Charger, as shown.

3 Remove the skin side beige liner from the adhesive (only good for one fixation).

4 For best charging results, make sure the Charger is centered over the Stimulator. If the Charger is not centered, charging time may increase. See sections *Properly Aligning the Charger* and *Tips for Properly Aligning the Charger* to ensure you center the Charger over the Stimulator. It is recommended that you follow the instructions in both sections the first time you charge your Stimulator.

***Note:*** *Do not put the Charger directly on the skin (e.g., without an Adhesive Patch).*

# Properly Aligning the Charger

1 Press the power button. The indicator light will come on again, and the Charger will begin beeping repeatedly to signal that it is searching for the Stimulator.

2 Position the Charger over the Stimulator.

The beeping will stop when the Charger is partially aligned with the Stimulator. For optimal charging, make sure the Charger is centered over the Stimulator.

Charging time may increase if the Charger is not fully aligned with the Stimulator. To fully align the Charger over the Stimulator, position the bottom curve of the Charger approximately 1 cm lower than the bottom curve of the Stimulator, as shown.

If you are having trouble properly aligning the Charger or experiencing longer than normal charging times, see section *Tips for Properly Aligning the Charger.*

3 Secure the Charger over the Stimulator either by pressing the adhesive to the skin over the Stimulator, or letting go of the Charging Collar.

***Note:*** *If the Adhesive Patch is accidentally located in the wrong place, or if the Charging Collar moves out of alignment, the Charger will start beeping again. Use a new Adhesive Patch or readjust the Charging Collar to place the Charger back into the fully aligned position.*

***Note:*** *Moving around while charging is acceptable, but be aware that the Charger must stay centered over the Stimulator for proper charging. Excessive movement may cause the Charger and Stimulator to become misaligned.*

4 When the Charger emits a distinct double beep, press the power button to turn off the Charger and check the Stimulator's battery with the Remote Control.

5 If the Stimulator is fully charged, remove the Charging Collar or Adhesive Patch from your body.

6 Separate the Charger from the Charging Collar or Adhesive Patch. Set aside the Charging Collar or discard the Adhesive Patch.

7 Return the Charger to the Base Station.

***Note:*** *Do not confuse the end of charge signal (a distinct double beep) with repeated beeping indicating misalignment.*

# Tips for Properly Aligning the Charger

If you are having trouble properly aligning the charger or are experiencing longer than normal charging times, you can use the following procedure to help you properly align the Charger.

1 Lightly press on your skin until you find the implanted Stimulator.

2 Press the Power Button on the Charger. The Charger will begin beeping repeatedly to signal that it is searching for the Stimulator.

3 Place the Charger to the left of the Stimulator.

4 Slowly move the Charger to the right, towards the Stimulator.

5 Stop moving the Charger when it stops beeping.

6 Make a mark on your skin with a soft-tipped marker at the right edge of the Charger, as shown.

7 Place the Charger to the right of the Stimulator.

8 Slowly move the Charger to the left, towards the Stimulator.

9 Stop moving the Charger when it stops beeping.

10 Make a mark on your skin at the left edge of the Charger, as shown.

11 Place the Charger above the Stimulator.

12 Slowly move the Charger down, towards the Stimulator.

13 Stop moving the Charger when it stops beeping.

14 Make a mark on your skin at the bottom edge of the Charger, as shown.

15 Place the Charger below the Stimulator.

16 Slowly move the Charger up, towards the Stimulator.

17 Stop moving the Charger when it stops beeping.

18 Make a mark on your skin at the top edge of the Charger, as shown.

The marks on your skin should create a square or crosshair. The center of this crosshair indicates the center of the Stimulator.

19 Now that you have located the center of the Stimulator, properly align the Charger over the Stimulator as shown.

# Cleaning Instructions

**Cleaning the Charger, Base Station, and Power Supply.** The components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Residue from soapy detergents should be removed with a damp cloth. Do not use abrasive cleansers for cleaning. Do not clean the Charger, Base Station, or Power Supply while they are connected to a power outlet.

**Cleaning the Charging Collar.** Hand wash the Charging Collar with mild soap and warm water. Do not machine wash the charging collar. Let the Charging Collar air dry. Be sure to remove the Charger and Counterweight from the Charging Collar before washing the Charging Collar.

# Technical Support

There are no user serviceable parts. If you have a specific question or issue, please contact your healthcare professional. If you need to contact Boston Scientific for any other reason, please call (833) DBS-INFO or (833) 327-4636.

Boston Scientific

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