Boston Scientific

Advancing science for life™

Vercise Genus™

Deep Brain Stimulation System

Information for Patients

92438796-03
Content: MP92438796-03 REV A

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

92438796-03

How to Use this Manual

This manual provides information about the Vercise Genus™ Deep Brain Stimulation (DBS) System.

Read all instructions carefully before using the Vercise Genus DBS System. Refer to your *Remote Control Handbook* and *Vercise DBS Charging Handbook* for additional instructions and information about your Vercise Genus DBS System. Refer to the *Labeling Symbols* document for an explanation of labeling symbols.

References to the Charging System or charging processes are applicable only when using a rechargeable DBS Stimulator.

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.

Trademarks

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Warranty

For device warranty information, visit www.bostonscientific.com/warranty.

Technical Support

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

Patient Identification Card

Ensure that you have received your Temporary Patient Identification Card. If not, contact your healthcare provider. Keep your Temporary Patient Identification Card with you until you receive your Permanent Patient Identification Card.

IMPORTANT CONTACT INFORMATION

For easy reference, note the contact information for your healthcare providers below:

Neurosurgeon _____

Neurologist _____

Caregiver _____

Information for Patients, Family Members, and Caregivers

- Boston Scientific recommends that you read this entire patient manual. It is unsafe to start using the device before reading the whole manual. If you have any questions about the information provided in this manual, contact your healthcare provider.
- **Always inform your healthcare providers that you have been implanted with a brain stimulation device.** If your healthcare providers have questions about your DBS system, they should contact Boston Scientific Technical Support. The Technical Support number is provided at the beginning of this manual.
- If you have any questions or concerns about your DBS therapy, contact your healthcare provider. If there is an emergency, call 9-1-1 or local emergency services.

Table of Contents

Introduction

The Boston Scientific Vercise Genus DBS System provides a reversible therapy where structures in the brain are stimulated with small electrical pulses (Figure 1). The Vercise Genus DBS System includes either a rechargeable Stimulator or a non-rechargeable Stimulator.

Note: *Some patients may have their Stimulator implanted in the abdomen.*

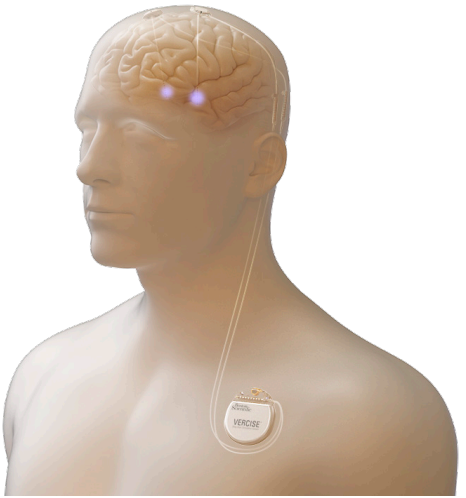

Figure 1. Illustration of the Implanted DBS System (Pectoral Region)

Intended Use / Indications for Use

The Vercise Genus DBS System is indicated for use in the following:

- 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.
- Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.
- Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

Description of the System

The Vercise Genus DBS System includes both implantable and non-implantable components. There are three main implantable components:

- **DBS Leads:** The DBS Leads are thin, insulated wires that deliver electrical pulses to the brain. The body of the DBS Leads is implanted under the scalp and the other end of the Lead is connected to the DBS Lead Extension, typically behind the ear.

- **DBS Lead Extensions:** Lead Extensions are thin, insulated wires that connect the Leads to the Stimulator. One end of the Lead Extension is connected to the Lead, typically behind the ear, and the other end is connected to the Stimulator. The Lead Extension transfers the electrical stimulation from the Stimulator to the Lead.
- **Stimulator:** The Stimulator sends small electrical pulses to the end of the DBS Lead that is implanted in the brain to produce stimulation in the brain. The Stimulator may be placed under the skin in the chest area or in the abdominal area. After your DBS surgery, your healthcare provider will adjust the stimulation settings for your Stimulator.

  The Stimulator contains either a rechargeable or non-rechargeable battery that supplies power to your DBS System. If you are using a Stimulator with a rechargeable battery, you will be able to recharge the battery using the DBS Charging System.

The Vercise Genus DBS System has two main non-implantable components:

- **Remote Control:** The Remote Control is a hand-held programmer that is used to control the Stimulator.
- **Charging System:** The Charging System is used to replenish the battery of rechargeable DBS Stimulators.

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

- How to live safely with the your Vercise Genus DBS System.
- How to use the Remote Control.
- How to use the Charging System to recharge the Stimulator, if you are using a rechargeable DBS Stimulator.

Note: *The Vercise Genus DBS System components were not made with natural latex.*

Rechargeable Stimulator Battery Information

For information regarding how to charge your Stimulator, refer to the *Charging Handbook*. For information regarding how to check the status of your Stimulator battery and battery messages, refer to the *Remote Control Handbook*.

Stimulator Battery

The rechargeable Stimulator battery should provide at least five years of service. In many cases, the Stimulator battery should provide at least 15 years of service. Battery life is dependent on the stimulation settings and conditions.

Recharge Estimate

Boston Scientific recommends any recharge schedule that fits your schedule and lifestyle while maintaining sufficient charge to maintain stimulation. You should expect a daily recharging time of 5 to 30 minutes per day or a periodic recharging time of 30 minutes 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. Developing a recharge routine involves finding the right balance among the following:

- 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 Genus DBS System 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 default stimulation level. While you may want to follow these recommendations, you and your healthcare provider 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.

After years of service, the Stimulator may require shorter intervals between charges. The Stimulator will need replacement when stimulation no longer can be maintained with routine charging.

Note: *Variations in your charging routine should not affect or diminish the battery life of the Stimulator.*

Non-Rechargeable Stimulator Battery Information

For information regarding how to check the status of your Stimulator battery and battery messages, refer to the *Remote Control Handbook*.

Stimulator Battery

The longevity of the non-rechargeable Stimulator battery depends on the following factors:

- Programmed parameters
- System impedance
- Hours per day of stimulation
- Changes to stimulation made by the patient

For additional information on estimating the longevity of the non-rechargeable battery, consult with your healthcare provider.

Elective Replacement

When the battery in your non-rechargeable Stimulator is nearing depletion, the Stimulator will enter the Elective Replacement mode. The Elective Replacement Indicator (ERI) message will appear on the Remote Control. Contact your healthcare provider to report the ERI message screen.

The Stimulator will provide stimulation during this ERI period. However, failure to replace the Stimulator may lead to reduced programming capabilities, limited communication with the Stimulator, and end of stimulation. Changes made to the stimulation will not be saved, and stimulation will end soon. Batteries that have lasted 12 months or more without entering ERI mode will have a minimum of 4 weeks between entering ERI mode and reaching End of Battery Life. The Stimulator must be replaced to resume stimulation. Surgery is required to replace the implanted non-rechargeable Stimulator, although Leads may stay in place while the Stimulator is exchanged.

End of Service (End of Battery Life)

When the Stimulator battery is fully depleted, the End of Service (EOS) indicator message will appear on the Remote Control. Stimulation will not be available. Surgery is required to replace the implanted non-rechargeable Stimulator to continue receiving stimulation.

Safety Information

Contraindications (When the Vercise Genus DBS System Should Not Be Used)

The Vercise Genus 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 shortwave, microwave, and/or therapeutic ultrasound diathermy when implanted with the Boston Scientific DBS System, or any of the system components. The energy generated by diathermy can be transferred to the Boston Scientific DBS System, causing tissue damage in the brain resulting in severe injury or death.
- **Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS):** The safety of these therapies in patients implanted with the Vercise Genus DBS System has not been established. It is possible that the energy generated by these therapies can be transferred to the Vercise Genus DBS System, causing tissue damage that may result in severe injury or death.
- **Patient Incapability:** If you are unable to properly operate the Remote Control and Charging System (as applicable), then you should not be implanted with the Vercise Genus DBS System.
- **Poor Surgical Candidates:** The Vercise Genus 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 Genus DBS System should not be used in patients who experience unsuccessful test stimulation.

Warnings

Automobiles and Equipment

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

If your Vercise Genus DBS System stops 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.

Electromagnetic Interference

Strong electromagnetic fields can potentially turn stimulation off, cause temporary unpredictable changes in stimulation, or interfere with the communication of the Remote Control. If an electromagnetic field is strong enough to turn stimulation off, this will be temporary and stimulation may automatically return once the electromagnetic field is removed.

You should avoid or exercise care around the following:

- Theft detectors, tag deactivators and RFID devices, 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 that you move through the center of the detector as quickly as possible. Interference from these devices should not cause permanent damage to the implanted device.

- 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 security screener and advise the security staff that you have an implanted medical device. If you must proceed through the security screener, move through the security screener quickly and stay as far as allowed from the screener. Interference from these devices should not cause permanent damage to the implanted device.
- 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 systems 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 Wi-Fi routers, cordless phones, Bluetooth wireless streaming devices, baby monitors, and microwave ovens.

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 (Applicable only to rechargeable Stimulators)

The Charger should be handled with care. The Charger may become warm while charging the Stimulator. Failure to use the Charging Collar, Charging Belt, 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 healthcare provider.

High Stimulation Levels

High levels of stimulation may damage brain tissue. To ensure that stimulation levels remain safe, your healthcare provider will set the maximum and minimum stimulation levels allowed by the Remote Control.

Intracranial Hemorrhage

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

Magnetic Resonance Imaging

As a patient implanted with the Vercise Genus DBS System, you will be able to have an MRI examination when specific conditions are met. Conditions for an MRI are specified in the supplemental physician manual *ImageReady™ MRI Guidelines for Boston Scientific DBS Systems* that is available on the website www.bostonscientific.com/manuals.

It is important that your healthcare provider read this information in its entirety and determine all conditions are met before conducting and recommending an MRI examination.

External Devices: The external/non-implantable components of the Vercise Genus DBS System (Charging System, Remote Control, and accessories) are MR Unsafe. They must not be taken into any MR environment such as the MRI scanner room.

Other Implanted Stimulation Devices

Concurrent use of the Vercise Genus DBS Stimulator and other implantable stimulation devices, such as pacemakers, cardioverter defibrillators, or medication delivery pumps may result in interference with the operation of the devices. If you require concurrent implantable stimulation devices, careful programming of each system is necessary. If you have a concern or encounter a problem, contact your healthcare provider.

Pregnancy

It is unknown whether this device may cause complications with pregnancy and/or hurt an unborn baby.

Stimulator Damage

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

Suicide

New onset or worsening depression which may be temporary or permanent is a risk that has been reported with DBS therapy. Suicidal thoughts, suicide attempts, and suicide are events that have also been reported. Patients and caregivers should consider the following:

- Before the procedure, be sure you talk to your treating physician(s) if you have a history of depression, suicidal thoughts, or have attempted suicide. Be sure you understand the possible risks of new onset or worsening depression (including suicidal thoughts) as well as the potential clinical benefits of DBS therapy.
- After the procedure, if you notice unusual changes in mood or behavior (such as increased anxiety, sleeping problems, loss of interest in activities, feeling of hopelessness, mood swings, weight loss or weight gain), or impulse control, contact your physician. If you are having thoughts of suicide, contact your physician or emergency services immediately.
- It is important to attend on-going follow-up visits with your physician to manage your therapy.

Therapeutic Ultrasound

Implanted components of the Vercise Genus DBS System should not be exposed to therapeutic levels of ultrasound energy.

Unauthorized Modification

Unauthorized modification to the medical devices is prohibited. If the DBS devices are subjected to unauthorized modification, the integrity of the devices could be compromised and harm or injury to the patient could occur.

Precautions

Activities Requiring Coordination

Loss of coordination is a possible side effect of DBS therapy. You should use caution when doing activities that require coordination, even if you were able to do them before receiving therapy (for example, swimming).

Bathing

Patients should exercise reasonable caution when bathing.

Cell Phones and Other Portable RF Communication Devices

Interference caused by cell phones is not anticipated, but the full effects of interaction with cell phones are unknown at this time. Portable RF communications equipment (for example, mobile phones) should be kept a minimum distance of 6 inches (15 cm) from the area of the implanted device. If interference does occur, move the cell phone away from the implanted Stimulator or turn off the phone. If there is a concern or a problem is encountered, contact your healthcare provider.

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 and Charging System should not be disposed of by fire, as these components contain batteries which may explode when exposed to fire and cause injury. Used batteries should be disposed of in accordance with local laws and regulations.

Device Failure

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

Massage Therapy

You should avoid receiving massage therapy near the components of the implanted DBS System. If you receive massage therapy, inform the masseuse that you have an implanted device and show him/her where the Stimulator, DBS Lead 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 they are used in close proximity to the Stimulator:

- Diagnostic ultrasonic scanning is unlikely to damage the Stimulator if stimulation is turned off. Testing has been completed to applicable standards.
- Electrocautery – The use of a heated electric probe to stop bleeding during surgery. Electrocautery can potentially damage the Stimulator or may cause injury. If you are to undergo electrocautery, your healthcare provider should review and follow the electrocautery guidance provided in the *Information for Prescribers* manual.

- External Defibrillation – The use of electrically charged paddles to restart the heart in an emergency. Safe usage of external defibrillation has not been established in DBS patients. Defibrillation is unlikely to permanently damage the implanted device if stimulation is turned off and the defibrillator electrode does not come into contact with any component of the implantable device. Testing has been completed to applicable standards.
- Lithotripsy – High-output sound or shock waves often used to treat gall stones and kidney stones. High frequency signals directed near the Stimulator may damage circuitry.
- Radiation Therapy – Ionizing energy commonly used to treat cancer. Lead shielding should be used over the Stimulator to prevent damage from high radiation. Any damage to the DBS Stimulator 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 DBS Stimulator if stimulation is turned off.

If any of the above is required by medical necessity, the procedure(s) should be performed as far from the implanted components as possible. Ultimately, however, the System may require explantation as a result of severe injury or damage to the device.

Before having these procedures, medical therapies, or diagnostics, have your healthcare professional call the Boston Scientific Technical Support department for proper instructions, or have them refer to the guidance provided in the *Information for Prescribers DFU*.

Operating Temperature

The operating temperature of the Remote Control is 5 °C to 40 °C (41 °F to 104 °F). For proper operation, do not use the Charging System if the ambient temperature is above 35 °C (95 °F).

Other Models of External Devices

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

Post-Operative

After your surgery, the medical staff will ensure that you 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 DBS system operations, including instructions on how to turn stimulation on and off, how to charge the Stimulator's battery (if applicable), 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 healthcare provider before you are discharged from the hospital.
- A responsible adult 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 healthcare provider, 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 healthcare provider. Surgical sutures and staples will need to be removed by your healthcare provider in a follow-up visit.
- Follow the instructions provided by your healthcare provider on how to care for the dressing covering the area where the Stimulator is implanted.

Initiating your stimulation therapy may be delayed up to 2 months until swelling (edema) is resolved. The timing will depend on the judgement of your healthcare provider. Post-surgical swelling is expected to subside. If you experience continued swelling, contact your healthcare provider. 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 if you are using a rechargeable Stimulator.

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

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

Remote Control and Charging System Cleaning

The Remote Control and Charging System 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 and then wiped dry. Do not use abrasive cleansers for cleaning. Do not clean any of the devices while they are directly or indirectly connected to a power outlet.

Remove the Charger and Counterweight from the Charging Collar before washing. Remove the Charger from the Charging Belt before washing. Hand wash the Charging Collar or Charging Belt with mild soap and warm water. Do not machine wash the Charging Collar or Charging Belt. Let the Charging Collar or Charging Belt air dry. Do not use the Charging Collar or Charging Belt when it is damp or wet.

As an operator of these 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.

Stimulator Orientation

Never attempt to change the orientation of the Stimulator or turn over the Stimulator. Avoid touching the incisions or Stimulator site. If the Stimulator flips over in your body, it may be unable to communicate with the Remote Control or Clinician Programmer. If the rechargeable Stimulator flips over in your body, then it cannot be charged. If stimulation cannot be turned on after charging, contact your healthcare provider 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 healthcare provider.

Storage, Handling and Transport

Do not expose the Remote Control or Charging System (if applicable) to excessively hot or cold conditions. Do not leave these devices in your car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat. If the Remote Control or the Charging System are to be stored for an extended period of time, be careful that the storage temperature does not exceed -20 °C to 60 °C (-4 °F to 140 °F).

Handle the system components and accessories with care. Do not drop them or submerge them in water. Accessories, including the Remote Control and Charger, must be kept dry and protected from 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 them. Keep the Remote Control and Charger away from pets, pests, and children to avoid damage to these devices.

Adverse Events

Not all risks with the use of deep brain stimulation are known. The following is a list of known risks. 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, inform your healthcare provider as soon as possible.

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 cerebral spinal fluid (CSF) infection or inflammation
- 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 collection 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 Stimulator 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, psychosis, 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 Lead 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 Lead Extension) may move from the original implanted location or wear through the skin, which may require 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

Electromagnetic Compatibility

EN 60601-1-2 Classification Information

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

Table 1: Guidance and Manufacturer's Declaration Electromagnetic Emissions		
The Vercise Genus DBS System is intended for use in electromagnetic environment specified below. The customer or the user of the Vercise Genus 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 Genus 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 Genus 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	

Table 2: Guidance and Manufacturer's Declaration Electromagnetic Immunity

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

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Air: Remote Control and Charger: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: Remote Control and Charger: ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. ***Note:*** *Applies to external electrical components.*
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.

Note: *The Charger is used with a rechargeable DBS System only.*

Table 3: Guidance and Manufacturer's Declaration Electromagnetic Immunity

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

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz	Professional healthcare facility environment and home healthcare environment. 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 Genus DBS System is used exceeds the applicable RF compliance level above, the Vercise Genus 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 Genus DBS System.

Table 4: Immunity Testing RFID Readers		
The external electrical components of the Vercise Genus DBS System have been tested for immunity to interference from RFID readers per the following specifications.		
RFID Spec Per AIM 7351731	**Frequency**	**Test Level (RMS)**
ISO 14223	134.2 kHz	65 A/m
ISO/IEC 14443-3 (Type A)	13.56 MHz	7.5 A/m
ISO/IEC 14443-4 (Type B)	13.56 MHz	7.5 A/m
ISOAEC 15693 (ISO 18000-3 Mode 1)	13.56 MHz	5 A/m
ISO 18000-3 Mode 3	13.56 MHz	12 A/m
ISO/IEC 18000-7	433 MHz	3 V/m
ISO/IEC 18000-63 Type C	860-960 MHz	54 V/m
ISO/IEC 18000-4 Mode 1	2.45 GHz	54 V/m

Table 5: Manufacturer's Declaration
Proximity Fields

The Vercise Genus DBS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The users of the Vercise Genus DBS System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Vercise Genus DBS System as recommended below, according to the maximum output power of the communications equipment.

Proximity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guide
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended separation distance d = 30 cm
	450 MHz: 28 V/m @ FM modulation	28 V/m	
	710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
IEC 61000-4-3	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	Recommended separation distance d = 30 cm
	2450 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	

Note: *For the frequency bands in this table, use the specified recommended separation distance. The recommended minimum separation distance of 30 cm between portable and mobile RF communications equipment (transmitters) and the Boston Scientific DBS System apply to all other frequencies within the specified ranges.*

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.

Telemetry Information

The following parameters describe the wireless communication link between the Remote Control and the Implantable Pulse Generator or External Trial Stimulator:

- Frequency Band: 2.402 GHz to 2.480 GHz
- Modulation Type: GFSK
- Maximum Radiated Power: 5 dBm
- Protocol: Bluetooth Low Energy technology

Quality of Wireless Service

The Vercise Genus DBS System uses a Half-Duplex, direct point-to-point, primary-secondary communication system based on Bluetooth Low Energy technology with the typical communication ranges listed in Table 6:

Table 6: Quality of Wireless Service of the Configure Tab
Typical Range Between the Remote Control and Implanted Stimulator (IPG)
9.8 ft (3 m)

Data will be resent if not successfully received on supported devices. Sources of in-band high interference may result in slow connection, difficulty when pairing devices, or both. If you experience any of these, you may need to decrease the distance between the communicating devices. For information on how to improve connection issues, see the *"Troubleshooting Wireless Coexistence Issues"* section of this manual.

Timing

When a user initiates a communication session, the system will typically respond in 1 to 6 seconds. The typical data throughput during an active programming session will be more than 10 kbps.

Troubleshooting Wireless Coexistence Issues

Other wireless and RF technology based equipment operating in close proximity to a similar frequency band may degrade the range and responsiveness of the Vercise Genus DBS System. If you experience issues with the wireless communication behavior between the Remote Control and Stimulator, try the following steps to correct the behavior:

- Decrease the distance between the two devices if possible.
- Ensure there are no objects between the communicating devices.
- Move the communicating devices away from other equipment or devices that may cause interference, such as Wi-Fi routers, cordless phones, Bluetooth wireless streaming devices, baby monitors, and microwave ovens.

Wireless Security

The Vercise Genus DBS System utilizes Bluetooth Low Energy for communication. The Vercise Genus DBS System supported devices implement the following Bluetooth Low Energy security features:

- LE Privacy
- LE Secure Connections

Additionally, the Vercise Genus DBS System implements proprietary authentication and encryption that supports:

- Authenticated pairing sequences that are initiated by the healthcare provider.
- Establishing a bonded connection only after successfully completing the authentication sequence.
- Creating a validated and encrypted communication link during each connection with a previously paired device.

The additional application level authentication and encryption ensures that communication with the Stimulator is only accomplished by authorized Boston Scientific devices.

FCC Compliance

The following is federal government communications regulation information about the Vercise Genus 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 Boston Scientific 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.

Glossary

Adhesive Patch. A non-reactive skin patch that is designed to temporarily attach the Charger to the skin over the Stimulator site.

Adverse Event. An undesirable effect.

Amplitude. The measure of strength of delivered stimulation.

Base Station. A holder/power supply that supports the Charger and keeps it in a ready state for recharging the Stimulator (applicable only when using rechargeable DBS Stimulators).

Battery. The power source for your Stimulator.

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

Charger. A portable device used to recharge the battery of implanted rechargeable Stimulators.

Charging Belt. An accessory that holds the Charger over rechargeable Stimulators for proper charging.

Charging Collar. An accessory that holds the Charger over rechargeable Stimulators for proper charging.

Charging Spacer. A piece of material that may be placed, if directed by your healthcare provider, behind the Charger in the pocket of the Charging Collar or Charging Belt.

Charging System. The Charging System is used to replenish the battery of rechargeable DBS Stimulators.

Computerized Axial Tomography (CT or CAT) Scans. A procedure that creates a 3-D image of your brain or other parts of your body.

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

Contraindication. A condition under which the Vercise Genus DBS System should not be used because the risks outweigh any possible benefit.

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

Counterweight. A device placed in the Charging Collar on the opposite side of the Charger to balance the Charging Collar (applicable only when using rechargeable DBS Stimulators).

DBS Lead. An insulated wire that delivers the electrical stimulation pulses 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.

Elective Replacement Mode. The state of a Boston Scientific non-rechargeable Stimulator when the Stimulator battery is nearing depletion.

Electrical Stimulation. Electrical pulses created by the DBS Stimulator.

Electromagnetic Disturbance. Any electromagnetic event that can degrade the performance of a DBS device or system.

Electromagnetic Interference. Reduced performance of a transmission channel or system caused by an electromagnetic disturbance.

Fluoroscopy. An X-ray procedure used during surgery.

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

Idle Mode (Sleep Mode). A time-out period when the Remote Control is not being used.

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

Incision. A small surgical cut in the skin.

Indicator Light. A signal light on the Charger that is used to show the status of the Charger (applicable only when using rechargeable DBS Stimulators).

Level. A 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 to create pictures of areas inside the body.

Non-Rechargeable Stimulator. A Stimulator with a battery that cannot be recharged. When the battery is depleted, it must be replaced for stimulation to continue.

Paresthesia. A tingling sensation.

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

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

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

Rechargeable Stimulator. A Stimulator with a battery that can be recharged. When the battery is depleted, it must be recharged for stimulation to continue.

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

Stimulation. Low level electrical pulses that are applied to the brain.

Stimulator. A device that sends electrical pulses to the brain. The Stimulator is also referred to as the “Battery” or “Implantable Pulse Generator.”

Ultrasound. A procedure that uses high frequency sound waves to visualize structures inside the body.

Warning. A potential hazard that you must be aware of to avoid serious situations that may cause injury or death.

Boston Scientific

Advancing science for life™

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Boston Scientific

Advancing science for life™

Vercise™ PC and Vercise Gevia™

Deep Brain Stimulation Systems

Information for Patients

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Content: MP92104394-04 REV A

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

92104394-04

Trademarks

Vercise™, Vercise Gevia™, and ImageReady™ are trademarks of Boston Scientific Corporation or its affiliates.

All other trademarks are the property of their respective owners.

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 your *Remote Control Handbook* and *Vercise DBS Charging Handbook* for additional instructions and information about your DBS System. Refer to the *Labeling Symbols* document for an explanation of labeling symbols.

Warranty

For device warranty information, visit www.bostonscientific.com/warranty.

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.

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 _____

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 for your locality.
- 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 at the number provided for your locality. If there is an emergency, call 9-1-1 or local emergency services.

Table of Contents

Glossary

Adhesive Patch. Non-reactive 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.

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

Battery. The power source for your Stimulator. The battery can be either rechargeable or non-rechargeable depending on your type of Stimulator.

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

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

Charging Collar. A garment used to hold the Charger over the rechargeable 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 Spacer, Counterweight, Charging Collar and Adhesive Patches. The Charging System is used for recharging the rechargeable Stimulator.

Computerized Axial Tomography (CT or CAT) Scans. A procedure that creates a 3-D image of your brain or other parts of your body.

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.

Electrical Stimulation. Electrical pulses created by the Stimulator.

Elective Replacement Mode. The state of your nonrechargeable Stimulator when it is nearing depletion.

Electromagnetic Disturbance. Any electromagnetic phenomenon which can degrade the performance of a device or system.

Electromagnetic Interference. Degradation of the performance of a transmission channel or system caused by an electromagnetic disturbance.

Hibernation Mode. A state your rechargeable 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.

Non-Rechargeable Stimulator. A Stimulator with a battery that cannot be recharged. When the battery is depleted, it must be replaced for stimulation to continue.

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 DBS System.

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

Rechargeable Stimulator. A Stimulator with a battery that can be recharged. When the battery is depleted, it must be recharged for stimulation to continue.

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

Stimulation. Low level electrical pulses applied to the brain.

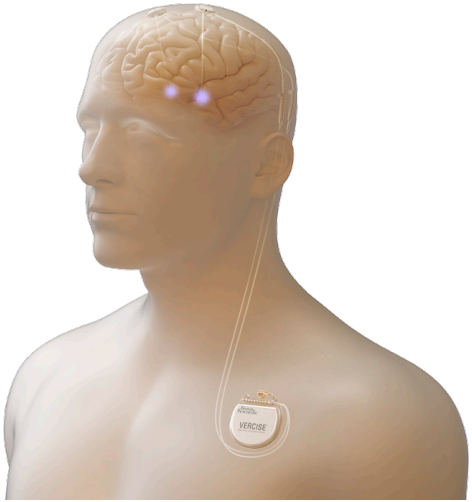
Stimulator. A device used to send electrical pulses to the brain. (Also referred to as the “Battery” or “Implantable Pulse Generator”).

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 DBS System is used for deep brain stimulation (DBS), a reversible therapy where structures in the brain are stimulated with small electrical pulses. The Vercise Gevia DBS System includes a rechargeable Stimulator. The Vercise PC DBS System includes a non-rechargeable Stimulator.



Descriptive Information

Intended Use / Indications for Use

The DBS System is indicated for use in the following:

- 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.
- Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.
- Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

Description of the System

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

- **DBS Leads:** 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.
- **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** 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. The Vercise Gevia DBS System includes a rechargeable Stimulator. The Vercise PC DBS System includes a non-rechargeable Stimulator.

There are also two external parts to your Vercise Gevia 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.

There is also one external part to your Vercise PC DBS System:

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

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

- How to live safely with the Vercise PC or Vercise Gevia DBS System.
- How to use the Remote Control.
- How to use the Charging System to recharge the Stimulator (for Vercise Gevia DBS System only).

Note: The DBS System was not made with natural latex.

Stimulator Battery Information

For information regarding how to check the status of your Stimulator battery and Battery Messages please refer to your Remote Control Handbook.

Vercise Gevia Stimulator (rechargeable)

The Vercise Gevia 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 Gevia 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 rechargeable Stimulator battery should provide at least five years of service. In many cases, the Stimulator battery should provide at least 15 years of service. Battery life is dependent on the stimulation settings and conditions.

After years of service, the Stimulator may require shorter intervals between charges. The Stimulator will need replacement when stimulation can no longer be maintained with routine charging.

Vercise PC Stimulator (non-rechargeable)

The Vercise PC Stimulator has a non-rechargeable battery. The longevity of the Stimulator battery depends on the following factors:

- Programmed parameters.
- System impedance.
- Hours per day of stimulation.
- Changes to stimulation made by the patient.

For additional information on estimating the longevity of the non-rechargeable battery consult with your physician.

Safety Information

When the Device Should Not be Used (Contraindications)

The 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 shortwave, microwave, and/or therapeutic ultrasound diathermy when implanted with the Boston Scientific DBS System, or any of the system components. The energy generated by diathermy can be transferred to the Boston Scientific DBS System, causing tissue damage in the brain resulting in severe injury or death.
- **Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS).** The safety of these therapies in patients implanted with the DBS System has not been established. It is possible that the energy generated by these therapies can be transferred to the DBS System, causing tissue damage that may result in severe injury or death.
- **Magnetic Resonance Imaging (MRI).** 

Patients implanted with the Vercise PC 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/or Charging System, then you should not be implanted with the DBS System.
- **Poor Surgical Candidates.** The 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.

Magnetic Resonance Imagining

For patients implanted with a Vercise Gevia DBS System Only: As a patient implanted with the Vercise Gevia DBS System, you will be able to have an MRI examination when specific conditions are met. These conditions are specified in the supplemental physician manual ImageReady™ MRI Guidelines for Boston Scientific DBS Systems available on the website www.bostonscientific.com/manuals.

It is important that your Physician read this information in its entirety and determine all conditions are met before conducting and recommending an MRI examination.

External Devices: Boston Scientific external components (i.e. Charger and Remote Control and accessories) are MR Unsafe. They must not be taken into any MR environment such as the MRI scanner room.

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, tag deactivators and RFID devices, 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 (Vercise Gevia DBS System only)

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

New onset or worsening depression which may be temporary or permanent is a risk that has been reported with DBS therapy. Suicidal thoughts, suicide attempts, and suicide are events that have also been reported. Patients and caregivers should consider the following:

- Before the procedure, be sure you talk to your treating physician(s) if you have a history of depression, suicidal thoughts, or have attempted suicide. Be sure you understand the possible risks of new onset or worsening depression (including suicidal thoughts) as well as the potential clinical benefits of DBS therapy.
- After the procedure, if you notice unusual changes in mood or behavior (such as increased anxiety, sleeping problems, loss of interest in activities, feeling of hopelessness, mood swings, weight loss or weight gain), or impulse control, contact your physician. If you are having thoughts of suicide, contact your physician or emergency services immediately.
- It is important to attend on-going follow-up visits with your physician to manage your therapy.

Stimulator Damage

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

Other Implanted Stimulation Devices

Concurrent use of the Stimulator and other implantable stimulation devices such as pacemakers, cardioverter defibrillators, or medication delivery pumps may result in interference with the operations of the devices. If you require concomitant implantable stimulation devices, careful programming of each system is necessary. If there is a concern or a problem is encountered, please contact your physician.

Automobiles and Equipment

Operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with caution after receiving the 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 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 cause complications with pregnancy and/or hurt an unborn baby.

Precautions

Other Models of External Devices

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

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

Stimulator Orientation

Never attempt to change the orientation of or turn over the Stimulator. Avoid touching the Stimulator site or incisions. 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.

If the Vercise Gevia 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.

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 2 months until swelling (edema) is resolved. The timing will depend on your physician's judgment. Post-surgical swelling is expected to subside. If you experience continued swelling, contact your physician. 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.

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 and Other Portable RF Communication Devices

Interference caused by cell phones is not anticipated, but the full effects of interaction with cell phones are unknown at this time. Portable RF communications equipment (for example, mobile phones) should be kept a minimum distance of 6 inches (15 cm) from the area of the implanted device. If interference does occur, move the cell phone away from the implanted Stimulator or turn off the phone. If there is a concern or a problem is encountered, 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. Stimulator function should be confirmed after the procedure. 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.
- MRI – A technique that uses magnetic fields and radio waves linked to a computer to create pictures of areas inside the body. If you have the Vercise Gevia DBS System you will be able to have an MRI examination when specific conditions are met. These conditions are specified in the supplemental physician manual ImageReady™ MRI Guidelines for Boston Scientific DBS Systems available on the website www.bostonscientific.com/manuals.
- If you have the Vercise PC DBS System you should not be subjected to MRI to avoid damage to the device and personal injury or even death.
- 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. Please refer to the contact list.

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 and Charging System should not be disposed of in fire, as this component contains batteries which may explode causing injury when exposed to fire. Used batteries should be disposed of in accordance with local laws and regulations.

Operating Temperature

The operating temperature of the Remote Control is 5 °C to 40 °C (41 °F to 104 °F). For proper operation, do not use the Charging System if the ambient temperature is above 35 °C (95 °F).

Storage, Handling and Transport

Do not expose the Remote Control or Charging System 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. If the Remote Control or the Charging System are to be stored for a period of time, be careful that the storage temperature does not exceed -20 °C to 60 °C (-4 °F to 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 and then wiped dry. Do not clean the Charger, Base Station or Power Supply while they are directly or indirectly connected to a power outlet.

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.

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.

Activities Requiring Coordination

Loss of coordination is a possible side effect of DBS therapy. You should use caution when doing activities that require coordination, even if you were able to do them before receiving therapy (for example, swimming).

Bathing

Patients should exercise reasonable caution when bathing.

Adverse Events

The following is a list of known risks with the use of deep brain stimulation. 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 cerebral spinal fluid (CSF) infection or inflammation
- 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 collection 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 Stimulator 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, psychosis, 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

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 PC and Vercise Gevia DBS Systems are intended for use in electromagnetic environment specified below. The customer or the user of the Systems should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Vercise Gevia 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. The Vercise PC 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 Gevia 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. The Vercise PC 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 PC and Vercise Gevia DBS Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the 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: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Air: Remote Control and Charger: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: Remote Control and Charger: ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. **Note**: Applies to external devices.
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 PC and Vercise Gevia DBS Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the DBS System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Professional healthcare facility environment and home healthcare environment. 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 DBS System is used exceeds the applicable RF compliance level above, the 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 DBS System.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Vercise PC and Vercise Gevia DBS Systems
The Vercise PC and Vercise Gevia DBS Systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 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 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: Vercise PC

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

- Typical range: 22 inches (55.8 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 (Remote Control)
  - The signal-to-noise ratio is measured before initiating a communication. Telemetry failures can occur if signal-to-noise ratio is low. Telemetry operations are retried for six seconds in case of insufficient range or in presence of interference. User is notified of the communication failure if the system has not been able to connect with the Stimulator within six seconds.
  - Packet and message errors are verified for accuracy. Any erroneous packets/messages are rejected and resent for up to six seconds. User is notified of the communication failure after six seconds of failed attempts.
  - User may re-try the command or follow on-screen instructions for telemetry help.

Quality of Wireless Service: Vercise Gevia

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

- Typical range: 36 inches (91.4 cm) between Remote Control and Stimulator with 95% or higher communication success rate.
- Timing: Once a command is initiated by the user, the system will respond in less than 1.5 seconds.
- Telemetry failures (Remote Control):
  - The signal-to-noise ratio is measured before initiating a communication. Telemetry failures can occur if signal-to-noise ratio is low. Telemetry operations are retried for six seconds in case of insufficient range or in presence of interference. User is notified of the communication failure if the system has not been able to connect with the Stimulator within six seconds.
  - Packet and message errors are verified for accuracy. Any erroneous packets/messages are rejected and resent for up to six seconds. User is notified of the communication failure after six seconds of failed attempts.
  - User may re-try the command or follow on-screen instructions for telemetry help.

Wireless Security

The Vercise PC and Vercise Gevia Systems have 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 kHz to 131 kHz
- Modulation type: FSK
- Effective Radiated Power: 0.05 mW (-13 dBm) maximum
- Magnetic Field Strength (at 3 m distance): 46 µA/m

FCC Compliance

The following is federal government communications regulation information about the Vercise PC and Vercise Gevia 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 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.

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Boston Scientific

Advancing science for life™

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