Boston Scientific

Advancing science for life™

Vercise™ Deep Brain Stimulation Systems

Information for Prescribers

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

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How to Use this Manual

This manual provides information about the Boston Scientific Deep Brain Stimulation (DBS) System. Throughout this manual, the name “Boston Scientific DBS System” refers to the following: Vercise Genus™, Vercise Gevia™, and Vercise™ PC Deep Brain Stimulation Systems.

Read all instructions carefully before using the DBS System. For other device-specific information not included in this manual, refer to the appropriate DFU for your Boston Scientific DBS System as listed in your *DBS Reference Guide*.

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.

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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, please contact your sales representative or call (833) DBS-INFO or (833) 327-4636.

Registration Information

Device registration information must be provided to Boston Scientific following device implantation. The purpose of this registration is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted DBS Lead, accessory, or device to gain quick access to pertinent data from the manufacturer.

To complete device registration, follow the instructions provided by your local sales representative or fill out the registration form included in the package contents. A device registration form is included with each Boston Scientific DBS Lead, DBS Extension, and some DBS Stimulators. Return one copy to the Boston Scientific Customer Service Department, keep one copy for patient records, provide one copy to the patient, and save one copy for the physician.

Boston Scientific Neuromodulation Corporation
Attention: Customer Service Department
25155 Rye Canyon Loop
Valencia, CA 91355, USA

Patient Identification Card

Ensure that the patient receives a completed Temporary Identification Card after their surgery. Permanent ID cards will be mailed directly to the patient following patient registration.

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Device Description

The Boston Scientific Deep Brain Stimulation (DBS) System provides a reversible therapy where structures in the brain are stimulated with small electrical pulses. A Boston Scientific DBS System utilizes current steering (also known as multiple independent current control or MICC) across eight or sixteen Contacts per DBS Lead to provide precise positioning of stimulation. The implantable components of the Boston Scientific DBS System include the following:

- An Implantable Pulse Generator (IPG) that is either rechargeable or non-rechargeable.
  - The IPG is also referred to as a Stimulator.
- Leads that deliver electrical pulses to the brain.
- Lead Extensions that connect the Leads to the IPG.
- A Lead Boot to protect the proximal end of the Lead between surgeries.
- Sutures Sleeves to protect the Lead and/or to anchor the Leads and Lead Extensions.
- Port Plugs for unused IPG or Lead Extension ports.
- The Boston Scientific SureTek™ Burr Hole Cover that may be used to anchor the Leads.

The non-implantable components of the Boston Scientific DBS System include the following:

- An External Trial Stimulator (ETS) and OR Cables that may be used for intraoperative testing.
- A Clinician Programmer (CP) that is used to set and adjust stimulation parameters.
  - A Pairing Magnet is used to facilitate first-time pairing between a Vercise Genus IPG and CP and/or Remote Control.
  - A Programming Wand is used to connect the CP to Vercise Gevia and Vercise PC IPGs.
- A Tunneling Tool that is used to create a subcutaneous tunnel for the Leads and Lead Extensions.
- External patient devices, such as the Remote Control that is used to communicate with the IPG, and a Charging System to recharge the battery of rechargeable IPGs.
  - The Charging System is only applicable for rechargeable IPGs.

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

Intended Use / Indications for Use

The Boston Scientific 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.

Safety Information

Contraindications

The Boston Scientific DBS System, or any of its components, is contraindicated for the following:

Diathermy: Shortwave, microwave, and/or therapeutic ultrasound diathermy should not be used on patients 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 Boston Scientific DBS System has not been established. It is possible that the energy generated by these therapies can be transferred to the Boston Scientific DBS System, causing tissue damage that may result in severe patient injury or death.

Magnetic Resonance Imaging (MRI) (Vercise PC Only): Patients implanted with the full Vercise PC DBS System (DBS Leads, Lead Extensions, and Stimulator) should not be subjected to MRI. MRI exposure may result in the following:

- Dislodgement of implanted components.
- Heating of the Contacts or other system components, causing permanent tissue lesioning.
- Damage to the Stimulator's electronics.
- Current induction through the DBS Leads and Vercise PC DBS System causing unpredictable levels of stimulation.
- Distortion of the diagnostic image.
- Personal injury or death.

Note: *The Vercise DBS Lead-Only System (before Stimulator is implanted), the Vercise Gevia System, and the Vercise Genus System are MR Conditional. An MRI examination can be conducted safely when all the instructions in the supplemental manual ImageReady™ MRI Guidelines for Boston Scientific DBS Systems are followed.*

For the latest version of the manual, go to http://www.bostonscientific.com/manuals.

Patient Incapability: Patients who are unable to properly operate the Remote Control and Charging System (when applicable) should not be implanted with the Boston Scientific DBS System.

Poor Surgical Candidates: The Boston Scientific DBS System is not recommended for patients who are poor surgical candidates.

Unsuccessful Test Stimulation: The Boston Scientific DBS System should not be used in patients who experience unsuccessful test stimulation.

Warnings

Automobiles and Equipment: Patients should operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with caution after receiving the Boston Scientific DBS System. Patients should avoid performing activities that would be dangerous if treated symptoms were to return, or in which stimulation changes could occur.

Charge Density: High levels of stimulation may damage brain tissue. To maintain safe limits, the DBS programming software will display a message when the stimulation level selected would exceed the safe limit, and programming of these settings will be prevented.

Patients may be granted the ability to change stimulation amplitude with the Remote Control within clinician-defined limits. The software prevents patient-controlled amplitude from exceeding the limit.

DBS Extension Connector: Implanting the DBS Lead Extension Connector in the soft tissue of the neck may increase the chance of DBS Lead breakage. Boston Scientific recommends placing the DBS Lead Extension Connector behind the ear such that glasses or headgear do not interfere with the implanted DBS System.

Electromagnetic Interference: Strong electromagnetic fields can potentially turn stimulation off, cause temporary unpredictable changes in stimulation, or interfere with Remote Control communication. 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. Patients should be advised to 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. Patients should proceed with caution, ensuring that they move through the center of the detector as quickly as possible. Interference from these devices should not cause damage to the implanted device.
- Security screeners, such as those used in Airport Security or at entrances to government buildings, including hand-held scanners. Patients should request assistance to bypass the security screener and advise the security staff that they have an implanted medical device. If patients must pass through the security screener, they should move through the security screener quickly and stay as far as allowed from the screener. Interference from these devices should not cause 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.
- For DBS devices not using Bluetooth technology for communication, 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.

- For DBS devices using Bluetooth technology for communication, 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 to them, 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: Patients should not charge while sleeping. This may result in a burn. The Charger may become warm while charging the Stimulator. The Charger should be handled with care. Failure to use the Charging Collar, Charging Belt, or an Adhesive Patch while charging, as directed, may result in a burn. If the patient experiences pain or discomfort, they should stop charging and contact their healthcare provider.

Intracranial Hemorrhage: Special precautions should be taken for patients who are prone to hemorrhage, including patients with coagulopathy, high blood pressure, or those who are using prescribed anticoagulants. Microelectrode penetration and DBS Lead insertion can put patients who have a likelihood of intracranial hemorrhages at greater risk.

Magnetic Resonance Imaging (MRI): The Vercise Genus and Vercise Gevia DBS Systems are "MR Conditional." This means that an MRI examination can be conducted safely using a 1.5 Tesla horizontal closed bore MRI system when all instructions and safety information in the supplemental manual *ImageReady™ MRI Guidelines for Boston Scientific DBS Systems* are followed.

The *ImageReady™ MRI Guidelines for Boston Scientific DBS Systems* manual appears on the Boston Scientific website www.bostonscientific.com/manuals or may be provided in your region. It is important to read the information in this supplemental manual in its entirety before conducting or recommending an MRI examination on a patient with a Boston Scientific DBS System.

External Devices: The external/non-implantable components of the Boston Scientific DBS System (External Trial Stimulator, ETS Adapter, OR Cables, Remote Control, Charging System, Clinician Programmer, and accessories) are MR Unsafe. They must not be taken into any MR environment such as the MRI scanner room.

Other Active Implantable Devices: Concurrent use of Stimulators such as the Boston Scientific DBS Stimulator and other active implantable devices, such as pacemakers, cardioverter defibrillators, or medication delivery pumps may result in interference with the operation of the devices. If the patient requires concomitant implantable active devices, careful programming of each system is necessary.

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 housing is ruptured or pierced, exposing the patient's tissue to battery chemicals. Do not implant the Stimulator if the housing is damaged.

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

- Preoperatively, assess patients for the risks of depression and suicide. This assessment should consider both the risk of depression and suicide as well as the potential clinical benefits of DBS therapy for the condition being treated.
- Postoperatively, actively monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control.
- If a patient experiences new or worsening depression or suicidal ideation, manage these symptoms appropriately.
- Educate patients and caregivers about these potential risks prior to implantation, and be sure that they know about the importance of ongoing support and follow-up, including when to contact their health care provider.

Therapeutic Ultrasound: Implanted components of the Boston Scientific DBS System should not be exposed to therapeutic levels of ultrasound energy. The implanted device may concentrate the ultrasound field and may cause patient harm.

Unauthorized Modification: Unauthorized modification to the medical devices is prohibited. The integrity of the DBS System could be compromised and harm or injury to the patient could occur.

Precautions

Physician training is required for usage of the Boston Scientific DBS System. The implanting physician should be experienced in the subspecialty of Stereotactic and Functional Neurosurgery. The following is a list of precautions that should be taken when implanting or using the DBS Stimulator.

Bathing: Patients should exercise reasonable caution when bathing.

Cell Phones and Other Portable RF Communication Devices: While interference caused by cell phones is not anticipated, the full effects of interaction with cell phones are unknown at this time. Patients should be instructed that 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 cell phone. If there is a concern or a problem is encountered, patients should contact their healthcare provider.

Cleaning the Charging Belt or Charging Collar: Do not machine wash the Charging Belt or Charging Collar.

Cleaning the Remote Control, External Trial Stimulator, Charger, Base Station, Power Supply, and Programming Wand: Do not use abrasive cleansers for cleaning. Do not clean any of the accessories while they are directly or indirectly connected to a power outlet.

As an operator of the external devices, perform only the following maintenance tasks on the external devices:

- Changing the battery
- Charging the battery
- Cleaning

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

Component Removal, Disposal, and Return: 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 Charger should not be disposed of in fire, as these devices contain batteries which may explode causing injury when exposed to fire. Used batteries should be disposed of in accordance with local laws and regulations.

Dispose of non-implantable components and packaging in accordance with hospital, administrative, and/or local government policy.

Components: The use of components other than those approved and/or supplied by Boston Scientific and intended for use with the Boston Scientific DBS System may damage the DBS System, diminish the effectiveness of therapy, and/or put the patient at unknown risk.

Connections: Before inserting any DBS Lead or DBS Lead Extension into any Connector or Header ports, including the Stimulator Header, DBS Lead Extension Connectors, and OR Cable Assembly, always wipe the DBS Lead with a sterile, dry cotton sponge. Contamination inside the Connector or Header ports may be difficult to remove and can cause high impedances, preventing electrical connectivity which may compromise the integrity of the stimulation circuit.

Device Failure: Implants can fail at any time due to random component failure, loss of battery functionality, or DBS Lead breakage. Stopping brain stimulation suddenly can cause serious reactions to develop. If the Stimulator stops working, patients should be instructed to turn off the Stimulator and contact their healthcare provider immediately so that the system can be evaluated and appropriate medical care can be given to manage the return of symptoms.

Environmental Precautions: Patients should avoid activities that could potentially involve large amounts of electromagnetic interference. Devices that contain permanent magnets, such as speakers, should not be placed near the Stimulator because they may cause the DBS System to turn on or off.

Excess DBS Extension: Coil excess DBS Lead Extension around or below the Stimulator. Excess wire on top of the Stimulator may increase the potential for communication interference, tissue erosion, or damage during Stimulator replacement surgery.

Inspect Packaging Before Use: Check the expiration date on the package before opening the sterile package and using the contents. Do not use the contents if the current date is past the expiration date, if the package is opened or damaged, or if contamination is suspected because of a defective sterile package seal.

- Inspect the seal integrity of the outer tray before use.
- Open the inner tray in the sterile field.
- If the Stimulator was dropped, do not implant it in a patient. The dropped Stimulator may have lost sterility, experienced a loss of hermeticity, or been otherwise damaged. Replace the dropped Stimulator with a new, sterile Stimulator prior to implantation. Return the damaged Stimulator to Boston Scientific.
- Do not use any component that shows signs of damage.
- Do not use if “Use By” date has expired.

Massage Therapy: Patients should avoid receiving massage therapy near the implanted system components. If a patient does receive massage therapy, the patient should inform the masseuse that they have an implanted device and show him/her where the Stimulator, DBS Lead Extensions, and DBS Leads are located. The patient should advise the masseuse to 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, or may cause injury to the patient. 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 because of damage to the device or patient harm.

- Diagnostic ultrasonic scanning is unlikely to damage the Stimulator if stimulation is turned off. Testing has been completed to applicable standards.
- Electrocautery – Electrocautery can transfer destructive current into the DBS Leads and/or Stimulator. See additional instructions below. Bipolar or monopolar electrocautery may be used. Electrocautery probes must be kept a minimum of 1 inch away from the implanted device.
- External Defibrillation – Safe usage of external defibrillation has not been established in DBS patients. Defibrillation of the patient 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 frequency signals directed near the Stimulator may damage circuitry. See additional instructions below.
- Radiation Therapy – Lead shielding should be used over the Stimulator to prevent damage from high radiation. 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.

If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation energy, ultrasonic scanning, X-ray, or CT scan, observe the following:

- Turn off stimulation at least five minutes before the procedure application.
- All equipment, including probes, ground plates and paddles, must be used as far away from the Stimulator as possible and oriented such that energy is not directed through or across the Stimulator, Leads, or Lead Extensions.
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the Stimulator.
- Equipment should be set to the lowest energy setting clinically indicated.
- Confirm the system is functioning properly following the procedure. Turn stimulation on and observe for the return of therapy to confirm functionality.

Operating Temperature: The operating temperature of the External Trial Stimulator, Remote Control, and Programming Wand 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, Charging System (as applicable), and Clinician Programmer that were provided with the Boston Scientific DBS System should be used with the Boston Scientific DBS System. Other models of these devices will not function with the Boston Scientific DBS System.

Patient Activities Requiring Coordination: Loss of coordination is a potential side effect of DBS therapy. Patients should exercise reasonable caution when participating in activities requiring coordination, including those that they were able to perform prior to receiving DBS therapy (e.g., swimming).

Patient Activity Following Surgery: During the two weeks following surgery, it is important for the patient to exercise extreme care so that appropriate healing will secure the implanted components. During this period, the patient should not attempt to move heavy objects. Instruct the patient to restrict head movements, including extension or flexion of the neck and rotation of the head, until healing is complete.

Setscrews: Before tightening Setscrews, always test impedance to confirm electrical connectivity. Tightening a Setscrew onto a Lead Contact may damage the Contact and may result in the need to replace the DBS Lead or DBS Lead Extension.

Single Use Only, Do Not Resterilize: For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Sterilization: Contents of the surgical kits are supplied sterile using an ethylene oxide process. Do not use if sterile barrier is damaged. If damage is found, call Boston Scientific Technical Support and return the damaged part to Boston Scientific.

Stimulator Orientation: Orient the Stimulator parallel to the skin surface. Suboptimal placement of the Stimulator may result in a revision surgery. Patients should avoid touching the Stimulator site or incisions. If patients notice a change in the appearance of the skin at the Stimulator location, such as the skin becoming thin over time, they should contact their healthcare provider.

In order to ensure effective device communications, including device programming, and proper charging, perform the following:

- For rechargeable IPGs, orient the Stimulator parallel to the skin surface and at a depth less than 2 cm and greater than 0.5 cm below the skin.
- For non-rechargeable Vercise Genus IPGs, orient the Stimulator parallel to the skin surface and at a depth less than 2.5 cm below the skin to ensure effective device communication.
- For the non-rechargeable Vercise PC IPG (DB-1140-S), orient the Stimulator parallel to the skin surface. There is no depth restriction for the Vercise PC IPG.
- The etched writing “This Side Up” must be facing out of the pocket toward the patient’s skin.

Suboptimal placement of the Stimulator may result in the inability to communicate with the device or inability to recharge and may require a revision surgery.

Patients should be instructed not to change the orientation of or turn over the Stimulator. If the Stimulator flips over in the body, then it cannot communicate or be charged. If stimulation cannot be turned on after charging, the Stimulator may have changed orientation or rotated; patients should contact their healthcare provider to arrange an evaluation of the system.

Storage, Handling, and Transport: Store implanted components, such as the Stimulator, Leads, and Lead Extensions, between 0 °C to 45 °C (32 °F to 113 °F) in an area where they are not exposed to liquids or excessive moisture. Temperatures outside of the stated range can cause damage. If stored in conditions beyond the required storage temperature, do not use the components and return to Boston Scientific.

The non-rechargeable Stimulator will enter storage mode if its temperature falls below 5 °C. When the Stimulator is in storage mode, it will not connect to a Remote Control or Clinician Programmer. To exit storage mode, increase the Stimulator temperature above 8 °C.

Store external components like the Remote Control, External Trial Stimulator, ETS Adapter, OR Cable and Extension (DB-4100-A and SC-4100-A), and Charging System between -20 °C to 60 °C (-4 °F to 140 °F). Store the Push-Button OR Cables (DB-4120-08 and DB-4120-16) between 0 °C to 45 °C (32 °F to 113 °F). Do not expose the external 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.

Handle the system components and accessories with care. Do not drop them or submerge them in water. Avoid all sources of water that could come into contact with the devices. 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 and Charger away from pets, pests, and children to avoid damage to the devices.

Care must be taken to avoid damaging the DBS Lead with sharp instruments or excessive force during surgery. The following guidelines will help to ensure the longevity of components:

- Do not sharply bend or kink the DBS Lead or Lead Extension.
- Do not tie Suture(s) directly to the DBS Lead or Lead Extension body.
- Avoid pulling an implanted DBS Lead taut; stress relief loops may help to minimize tension on the DBS Lead.
- Avoid handling the DBS Lead with sharp instruments; use only rubber-tipped forceps.
- Take care when using sharp instruments, such as hemostats or scalpels, to prevent damaging the DBS Lead.

Surgical Tape: If tape is used to temporarily secure the DBS Lead during surgery, caution should be used to ensure the Lead is not cut or damaged when removing the tape.

Sutures: Do not apply Sutures tightly around the DBS Leads, as this may damage the insulation of the DBS Lead and may result in DBS Lead failure.

Tissue Reaction: Temporarily, there may be some pain in the area of the Stimulator as the incisions heal. If there is excessive redness around the wound area, it should be checked for infection. In rare cases, adverse tissue reaction to implanted materials can occur.

Adverse Events

The following is a list of known risks with the use of deep brain stimulation. There may be 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 Lead during surgery.

If any of these events occur, patients should inform their 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) fluid 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 IPG implant

Possible Side-Effects of Stimulation

- Confusion or problems with attention, thinking, or memory
- Gait difficulty (trouble walking) and falls
- New onset or worsening depression, which may be temporary or permanent, and suicidal ideations, suicide attempts, and suicide

- 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

Service and Maintenance

External Trial Stimulator (ETS) Maintenance

The ETS may be used to conduct intraoperative stimulation testing during the Lead implantation procedure. Refer to the DFU listed in your *DBS Reference Guide* for detailed procedure and guidelines for intraoperative testing.

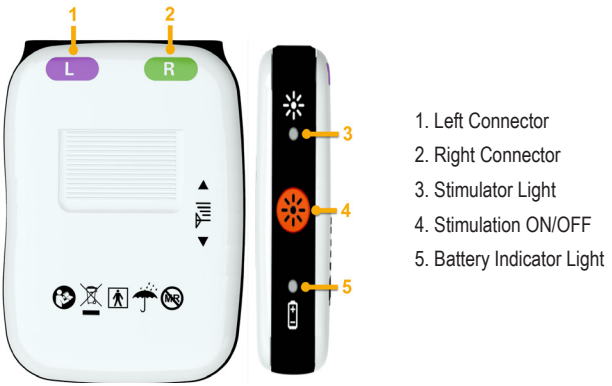

Figure 1. External Trial Stimulator

To turn stimulation on and off on the ETS, press and release the ON/OFF button on the ETS (Figure 1). When the stimulation is on, the Stim Indicator Light will blink green. The ETS runs on two AA batteries that are provided with every ETS kit. When the batteries need replacement, the Battery Indicator Light will change from a flashing green to a flashing yellow.

Ensure that stimulation is off (the indicator light is not blinking) before opening the ETS battery compartment.

To install new batteries in the ETS:

1. Confirm that stimulation is OFF by confirming that the stimulation indicator light is not blinking.
2. On the rear of the ETS, push in slightly and slide down the battery compartment cover.
3. Remove the old batteries.
4. Place two new AA batteries in the slots matching the positive (+) and negative (-) markings in the compartment.
5. Align the battery compartment cover on the case and slide the cover into position until is snaps closed.
6. Both the Battery Indicator light and the Stim On indicator lights will emit an amber glow for 15 seconds after which the Battery Indicator light blinks green.

Cleaning the Charging System

The components of the Charging System (Charger, Base Station, and Power Supply) 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 any of the accessories while they are directly or indirectly connected to a power outlet.

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

Cleaning the Remote Control

The components of the Remote Control 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 while directly or indirectly connected to a power outlet.

Cleaning the Programming Wand

The components of the Programming Wand 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 while directly or indirectly connected to a power outlet.

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 Boston Scientific DBS System is intended for use in electromagnetic environment specified below. The customer or the user of the Boston Scientific 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 Boston Scientific 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 Boston Scientific 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	

Table 2: Guidance and Manufacturer's Declaration Electromagnetic Immunity

The Boston Scientific DBS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Boston Scientific DBS System should assure 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 ETS and Wand: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV[1] Contact: Remote Control, Charger, and ETS 3: ± 8 kV ETS 2 and Wand: ± 6 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.*
Electrical fast transient/ burst IEC 61000-4-4 (Programming Wand only)	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 (Programming Wand only)	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

1 ± 15 kV compliance level applies to Vercise ETS 3 only.

Table 2 (Continued): Guidance and Manufacturer's Declaration Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 (Programming Wand only)	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Boston Scientific DBS System requires continued operation during power mains interruptions, it is recommended that the Boston Scientific DBS System be powered from an uninterruptible power supply or a battery.
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: *UT is the a.c. mains voltage prior to application of the test level.* ***Note:*** *The Charger is used with rechargeable DBS Systems only.* ***Note:*** *The Programming Wand is used with Vercise PC and Vercise Gevia DBS Systems only.*			

Table 3: Guidance and Manufacturer's Declaration Electromagnetic Immunity

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

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 (ETS only)	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 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	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 Boston Scientific DBS System is used exceeds the applicable RF compliance level above, the Boston Scientific 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 Boston Scientific DBS System.

Table 4: Immunity Testing RFID Readers		
The external electrical components of the Boston Scientific 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 Boston Scientific DBS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The users of the Boston Scientific DBS System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Boston Scientific 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

External Trial Stimulator

The stimulation pulse shall meet the requirements for charge balance and amplitude while stimulation is on.

Other External Devices

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

Telemetry Information

Vercise PC and Vercise Gevia DBS Systems

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

Vercise Genus DBS System

The following parameters describe the wireless communication link between the Remote Control or Clinician Programmer 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

Vercise PC and Vercise Gevia DBS Systems

The Vercise PC and Vercise Gevia DBS Systems use a Half-Duplex, direct point-to-point, primary-secondary communication system with the characteristics listed in Table 6:

Table 6: Quality of Wireless Service of the Configure Tab (Vercise PC and Vercise Gevia)

Boston Scientific Stimulator Type	Typical Range	
	Between the Remote Control and Stimulator	Between the Wand and Stimulator
Non-Rechargeable Stimulator	22 in (55.8 cm)	18 in (45.7 cm)
Rechargeable Stimulator	36 in (91.4 cm)	33 in (83.8 cm)

Vercise Genus DBS System

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 7:

Table 7: Quality of Wireless Service of the Configure Tab (Vercise Genus)

Typical Range			
Between the Remote Control and Implanted Stimulator (IPG)	Between the Remote Control and External Trial Stimulator (ETS)	Between the Clinician Programmer and Implanted Stimulator (IPG)	Between the Clinician Programmer and External Trial Stimulator (ETS)
9.8 ft (3 m)	19.6 ft (6 m)	9.8 ft (3 m)	19.6 ft (6 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 for Vercise PC and Vercise Gevia DBS Systems

Once a command is initiated by the user, the system will respond in less than 1.5 seconds.

Timing for Vercise Genus DBS System

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 Boston Scientific DBS System. If you experience issues with the wireless communication behavior between the Remote Control/Clinician Programmer and Stimulator, try the following steps to correct the behavior:

For Vercise PC and Vercise Gevia DBS Systems

- Decrease the distance between the two devices if possible.
- Change the orientation of the communicating device.
- Move the communicating devices away from other equipment or devices that may cause interference, such as television and computer monitors, short range RFID electronic tracking systems such as badge scanners and parking lot scanners, power adapters, and wireless chargers.

For Vercise Genus DBS System

- 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

Vercise PC and Vercise Gevia DBS Systems

The Vercise PC and Vercise Gevia DBS Systems have a short range inductively coupled telemetry system. A Remote Control (or Wand) has to be linked with a Stimulator to allow communication. The Stimulator will not respond to any unlinked device. There are additional mechanisms that ensure the integrity of the communicated data.

Vercise Genus DBS System

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.

Clinician Programmer Security

The Clinician Programmer (CP) is a hardened computer with the following security controls:

- Access to the CP is restricted to authorized users and the CP screen locks out if there is no activity and may only be unlocked with a password to prevent unauthorized access.
- The CP Platform enforces a password lockout duration after a predefined number of unsuccessful login attempts.
- Only authorized incoming connections are allowed.
- The encrypted file system restricts access of the data in the file system to authorized users only.
- Non-whitelisted applications cannot be installed.
- All BSN applications are code signed so that any compromise to their integrity via USB or other data channels may be detected and prevented from execution.
- User actions and login attempts are logged by the Windows Event Log.
- The CP logs and notifies the user upon detection of malicious software.

Boston Scientific has developed a process to receive potential product security vulnerabilities from external sources in order to validate their existence and determine how to best respond to improve product security and safety. Please refer to the following webpage to report potential product security vulnerabilities to the Boston Scientific Product Security team: https://www.bostonscientific.com/en-US/customer-service/product-security/responsible-disclosure.html

FCC Compliance

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

FCC ID

Vercise PC and Vercise Gevia IPG

FCC ID: Q4D-SC1132

Vercise Genus Rechargeable IPG

FCC ID: Q4D-SC1232

Vercise Genus Non-Rechargeable IPG

FCC ID: Q4D-SC1432

Rechargeable Stimulator Battery

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 the patient's schedule and lifestyle while maintaining sufficient charge to maintain stimulation. Patients 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 their recharge routine may vary depending on their stimulation parameters. High power users will require more frequent charging. Developing a patient's recharge routine involves finding the right balance among the following:

- How much power is required for the patient to experience effective therapy
- How often the patient wants to recharge
- How long the patient wants to recharge
- How the patient would like to manage their personal schedule

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.

The Clinician Programmer will provide a recharging estimate based on 24 hours per day of stimulation at the programmed settings. If fully charging the Stimulator, patients should be instructed to charge until the Charger emits the end of charge double beep.

Note: *For instructions on charging the Stimulator, refer to the appropriate Charging Handbook for your DBS System as listed in your DBS Reference Guide. For instructions on checking the Stimulator battery status, refer to the appropriate Remote Control DFU for your DBS System as listed in your DBS Reference Guide.*

Non-Rechargeable Stimulator Battery

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, refer to the appropriate *Programming Manual* as listed in your *DBS Reference Guide.*

Elective Replacement

When the implanted non-rechargeable Stimulator is nearing the end of its battery life, the Stimulator will enter the Elective Replacement mode. The Elective Replacement Indicator (ERI) will appear on the Remote Control and Clinician Programmer. Stimulation is still being provided during this ERI period. Changes made to the stimulation will not be saved, and stimulation will not be available soon. Patients should be advised to contact their healthcare provider to report this message screen. The Stimulator must be replaced to continue receiving stimulation. 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. 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 will be displayed on the Remote Control and Clinician Programmer. Stimulation will not be available. Surgery is required to replace the implanted non-rechargeable Stimulator to continue providing stimulation.

End of Programmed Service (Vercise PC Only)

The non-rechargeable Stimulator software has been programmed to end service after a defined period. When the Stimulator is within approximately 180 days of the end of its programmed period, the Remote Control and Clinician Programmer will display a message indicating the number of service days available. Refer to the *Remote Control DFU* listed in your *DBS Reference Guide* for description of the End of Service messages displayed.

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Boston Scientific

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