Brio™ Patient Programmer

User's Guide

ST. JUDE MEDICAL

⚠ CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For a listing of patents for St. Jude Medical neuromodulation products, visit http://patent.sjmneuro.com.

Contents

About This Guide

This guide explains how to use the St. Jude Medical™ Brio™ patient programmer (Model 6860) with your Brio neurostimulation system. If you have any questions about your system, contact Customer Service.

Symbols and Definitions

The following symbols are used in this document and on some of the products and packaging:

Symbol	Description
	Caution, Consult Accompanying Documents
	Denotes that the user must consult this document for important safety-related information (This symbol is blue and white on the device.)
	Denotes device contains a type BF applied part to protect you from shock. The device is internally powered and is intended for continuous operation.
	Denotes to keep the device dry
	Denotes expiration date
	Denotes date of manufacture
	Denotes temperature limits for storage conditions
	Denotes humidity limits
	Denotes pressure limits
REF	Denotes catalog number
	Denotes manufacturer
UNIT	Denotes content, the number of items contained in the package
PN	Denotes code that uniquely identifies an inventory item
SN	Denotes serial number
LOT	Denotes batch code
Rx only	Denotes for prescription use only

Symbol	Description
EC REP	Denotes authorized European representative
	Denotes that this product shall not be treated as household waste. Instead it is the user's responsibility to return this product to St. Jude Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact St. Jude Medical.
CE	European conformity
0123	The EU notified body number for AIMD
	This device is listed by the Canadian Standards Association (CSA) International as certified

Terms Used in This Document

This section contains definitions of some of the terms used in this document.

Amplitude. A measure of the strength of the stimulation in milliamps (mA).

Program. A combination of stimulation parameters that are set to get a desired therapeutic effect.

Stimulation parameter. A setting that is part of a complete program.

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This rechargeable neurostimulation system is intended to deliver electrical stimulation to targets in the brain. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use

The St. Jude Medical™ deep brain stimulation system is indicated for the following conditions:

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications.
- Unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

Contraindications

This system is contraindicated for patients who meet the following criteria:

- are unable to operate the system
- have unsuccessful test stimulation

The following procedures are contraindicated for patients with a deep brain stimulation system. Advise patients to inform their healthcare professional that they cannot undergo the following procedures:

- Diathermy (short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy)
- Electroshock therapy and transcranial magnetic stimulation (TMS)

Warnings

The following warnings apply to the Brio™ neurostimulation system.

Pregnancy and nursing. Do not use the Brio neurostimulation system if you are pregnant or nursing.

Magnetic resonance imaging (MRI). Do not perform an MRI on a patient with any implanted Brio neurostimulator or lead (or any portion of a lead). Even if the neurostimulator has been removed, the patient should not have an MRI if any part of a lead or the cranial prosthesis is still implanted. The Brio

neurostimulation system is MR unsafe. Testing has not been performed to define conditions of use to ensure safety of the Brio neurostimulation system in an MR environment.

Charge density. A risk of tissue damage exists with stimulation parameter settings of high amplitudes and wide pulse widths. Higher amplitude and pulse width settings required to achieve therapy may indicate a system problem or suboptimal lead placement. **Parameter values exceeding the charge density limit of 30 μC/cm² should only be programmed with due consideration of the warnings concerning charge densities.** Charge density can be reduced by lowering the stimulation amplitude or pulse width.

High stimulation outputs. Avoid excessive stimulation. There is a potential risk of brain tissue damage from high amplitude and wide pulse width parameter settings. Programming at high amplitudes and wide pulse widths should only be done with due consideration of the charge density warning. The system can be programmed to use parameter settings outside the range of those used in the clinical studies. If the programming of stimulation parameters exceeds charge density limits, a screen will appear warning you that the charge density is too high. For more information, see the "Troubleshooting" section in the programmer manual.

> **NOTE:**
>
> Higher amplitudes and wider pulse widths may indicate a system problem or a less than optimal lead placement. Stimulation at high outputs may cause unpleasant sensations or motor disturbances or may render the patient incapable of controlling the patient programmer. If unpleasant sensations occur, the device should be turned off immediately using the patient magnet.

Risk of depression, suicidal ideations, and suicide. Depression, suicidal ideation, and suicide have been reported in patients receiving deep brain stimulation therapy for movement disorders, although no direct cause and effect relationship have been established. Preoperatively, assess patients for suicide risk and carefully balance this risk with the potential clinical benefit. Postoperatively, monitor patients for the presence of depression, suicidal thoughts, or behaviors, changes in mood and/or impulse control and manage these symptoms appropriately. Emphasize the importance of sustained follow up and support with all patients and their caregivers and family members.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

Explosive or flammable gases. Do not use the patient programmer in an environment where explosive or flammable gas fumes or vapors are present. The operation of the patient programmer could cause them to ignite, causing severe burns, injury, or death.

Operation of machinery and equipment. Patients should not operate potentially dangerous machinery, power tools, or vehicles or engage in any activity that could be unsafe if their symptoms were to unexpectedly return.

Device components. The use of components that are not approved by St. Jude Medical with this system may result in damage to the system and increased risk to the patient.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted neurostimulation system. Contact between an active electrode and an implanted IPG, lead, or extension can cause severe injury to the patient. If the use of an electrosurgery device is necessary, turn off the IPG. Use a bipolar mode to limit the spread of the electrosurgical field.

Implant heating. While recharging an IPG, patients may perceive an increase in temperature. In patients who have areas of increased sensitivity to heat, consider placing the implant where the patient has normal sensation.

Radiofrequency or microwave ablation. Careful consideration should be used before using radiofrequency (RF) or microwave ablation in patients who have an implanted neurostimulation system since safety has not been established. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Implanted cardiac devices. There is a risk of possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Other active implanted devices. The neurostimulation system may interfere with the normal operation of another active implanted device, such as pacemaker, defibrillator and another type of neurostimulator. Conversely, the other active implanted device may interfere with the operation of the neurostimulation system.

Case damage. If the case of the implantable pulse generator (IPG) is pierced or ruptured, severe burns could result from exposure to battery chemicals.

Cremation. The IPG should be explanted before cremation because the IPG could explode. Return the explanted IPG to St. Jude Medical.

Component disposal. Return all explanted components to St. Jude Medical for safe disposal. IPGs contain lithium ion batteries as well as other potentially hazardous materials. Do not crush, puncture, or burn the IPG because explosion or fire may result.

Coagulopathies. Physicians should use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should also consider underlying factors, such as previous neurological injury or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

Low frequencies. Stimulation frequencies at less than 30 Hz may cause tremor to be driven (meaning that tremor occurs at the same frequency as the programmed frequency). For this reason, programming at frequencies less than 30 Hz is not recommended.

IPG placement. The IPG should be placed into the pocket, at a depth not to exceed 2.25 cm (0.9 in), with the logo side facing toward the skin surface. Placing the IPG deeper than 2.25 cm (0.9 in) can impede or prohibit IPG communications with the patient programmer or prevent charging with the charging system.

Return of symptoms and rebound effect. The abrupt cessation of stimulation for any reason, including failure to maintain adequate battery charge in rechargeable neurostimulators will probably cause a return of disease symptoms. In some cases, symptoms may return with an intensity greater than that was experienced prior to system implant (rebound effect). This can in rare cases constitute a medical emergency. For patients with rechargeable neurostimulators, it is important to emphasize the following:

- Patients must be willing and able to perform battery status checks and battery recharge activities on a frequent basis.
- The device charge level should be maintained such that symptoms are controlled.
- The recharge warnings from the patient programmer must be understood and heeded by the patient and caregiver.

Precautions

The following precautions apply to the Brio™ neurostimulation system.

General Precautions

Surgeon training. Implanting physicians should be experienced in stereotactic and functional neurosurgery.

Clinician training. Clinicians should be familiar with deep brain stimulation therapy and be experienced in the diagnosis and treatment of the indication for which the deep brain stimulation components are being used.

Patient selection. Select patients appropriately for deep brain stimulation. Consultation with the neurologist who will provide follow-up care is recommended prior to selection of a rechargeable neurostimulator. Compliance with checking the battery status regularly is critical. A practice period for the patient and associated caregiver prior to implant is suggested, to assess whether the patient will be willing and able to incorporate the required recharging activities into current activities of daily living. The following should be considered for the expected duration of the implant period:

- Patient's ability to use the patient programmer and correctly interpret the icons that appear on the screen.
- Patient's ability to regularly monitor the status of the rechargeable battery and respond appropriately.
- Patient's ability to accurately locate their implanted neurostimulator, properly position the recharge antenna for sufficient coupling, put on the recharge holster/belt, and monitor progress during the recharge session.
- Patient's ability to perform charging activities for sufficient duration and frequency to maintain therapy and to perform charging activities on an ongoing basis.

Special consideration should be given to the following:

- Available level of support from a caregiver, to assist the patient with monitoring and recharging activities.
- Expected effect from cessation of therapy, should patient fail to recharge on schedule or when alerted.
- Patient's age, as very young or very old patients may have difficulty performing required monitoring and recharging of the device.
- Patient's mental capacity, as patients with cognitive impairment or those prone to developing dementia would likely have difficulty performing device-related tasks without assistance.
- Patient's physical ability, as patients with higher degrees of motor impairment might have difficulty with the physical requirements of monitoring and recharging the device.

- Patient's visual ability, as patients need to be able to read the patient programmer or recharger display screen to assess battery status.
- Patient's willingness to use the patient programmer alert or a different method that will be effective in reminding the patient to check the battery status on a regular basis.
- Patient's (and caregiver's) willingness to continue recharging activities as necessary under all circumstances, (e.g., power outages, travel, and hospitalizations), and recognize the critical nature of maintaining a charged battery in the neurostimulator.

Infection. Follow proper infection control procedures. Infections may require that the device be explanted.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should move through the center of the detector quickly and then check the IPG to verify that it is turned on or off.

Stimulation parameters. Patients should be cautioned that stimulation parameters must be determined under the supervision of a physician and that they should not adjust stimulation parameters within prescribed programs except under direct orders from their physician.

Disconnecting the wand. Do not pull directly on the cord to disconnect the wand from the programmer. Doing so can damage the cord and make the wand inoperable. To disconnect the wand, grasp and gently pull the connector at the plug.

Damage to shallow implants. Falling and other traumatic accidents can damage shallowly implanted components such as the leads and extensions.

Keep the programmer dry. The programmer is not waterproof. Keep it dry to avoid damage. Do not use the programmer when engaging in activities that might cause it to get wet, such as swimming or bathing.

Handle the programmer with care. The programmer is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground.

Control of programmer. Keep the programmer away from children and pets in order to avoid potential damage or other hazards.

Battery care. Batteries can explode, leak, or melt if disassembled, shorted (when battery connections contact metal), or exposed to high temperature or fire.

Unauthorized programming changes. Do not make unauthorized changes to physician-established stimulation parameters. If you find yourself in an unfamiliar screen display, press the Previous Screen key.

Handling and Implantation

Expiration date. An expiration date (or "use-before" date) is printed on the packaging. Do not use the system if the use-before date has expired.

Care and handling of components. Use extreme care when handling system components. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to St. Jude Medical for evaluation.

Exposure to body fluids or saline. Prior to connection, exposure of the metal contacts, such as those on the connection end of a lead or extension, to body fluids or saline can lead to corrosion. If such exposure occurs, clean the affected parts with sterile, deionized water or sterile water for irrigation, and dry them completely prior to lead connection and implantation.

Skin erosion. To avoid the risk of skin erosion, implant components at the appropriate depth and inform patients to avoid touching their skin where components are implanted. The IPG should be placed into the pocket, at a depth not to exceed 2.25 cm (0.9 in), with the logo side facing toward the skin surface.

System testing. To ensure correct operation, the system should always be tested after implantation and before the patient leaves the surgery suite.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to St. Jude Medical for service.

Software upgrades. Unless otherwise noted, only St. Jude Medical personnel or an authorized representative may upgrade software.

Hospital and Medical Environments

Electrical medical treatment. In the case that a medical treatment is administered where an electrical current is passed through the body from an external source, first deactivate the IPG by setting all electrodes to off, turning stimulation off, and setting the amplitude to zero. Regardless if the device is deactivated, take care to monitor the device for proper function during and after treatment.

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotriptor, may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted system.

External defibrillators. The safety of discharging an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted IPG should be shielded with lead. Damage to the system may not be immediately detectable.

Effect on electrocardiograms (ECGs). Ensure the neurostimulator is programmed off prior to initiating an ECG. If the neurostimulator is on during an ECG, the ECG recording may be adversely affected, resulting in inaccurate ECG results. Inaccurate ECG results may lead to inappropriate treatment of the patient.

Home and Occupational Environments

Patient activities and environmental precautions. Patients should take reasonable care to avoid devices that generate strong EMI, which may cause the deep brain stimulation system to unintentionally turn on or off. Patients should also avoid any activities that would be potentially unsafe if their symptoms were to return unexpectedly. These activities include but are not limited to operating potentially dangerous machinery, power tools, vehicles, climbing ladders. Sudden loss of stimulation may cause patients to fall or lose control of equipment or vehicles, injure others or bring injury upon themselves.

Activities requiring excessive twisting or stretching. Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive

bending, twisting, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component.

Component manipulation by patient. Advise your patient to avoid manipulating the implanted system components (e.g., the neurostimulator, the burr hole site). This can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. Manipulation may cause device inversion, making a rechargeable neurostimulator impossible to charge.

Scuba diving or hyperbaric chambers. Patients should not dive below 10 m (33 ft) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 m (33 ft) of water (or above 2.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician.

Skydiving, skiing, or hiking in the mountains. High altitudes should not affect the neurostimulator; however, the patient should consider the movements involved in any planned activity and take precaution to avoid putting undue stress on the implanted system. Patients should be aware that during skydiving, the sudden jerking that occurs when the parachute opens may cause lead dislodgement or fractures, which may require surgery to repair or replace the lead.

Mobile phones. The effect of mobile phones on deep brain stimulation is unknown. Patients should be advised to avoid carrying mobile phones in their shirt pocket or otherwise placing them directly over the deep brain stimulation system components. If interference occurs, try holding the phone to the other ear or turning off the phone.

Household appliances. Household appliances that contain magnets (e.g., refrigerators, freezers, inductive cooktops, stereo speakers, mobile telephones, cordless telephones, standard wired telephones, AM/FM radios, and some power tools) may unintentionally cause the deep brain stimulation system to turn on or turn off.

Therapeutic magnets. Patients should be advised to not use therapeutic magnets. Therapeutic magnets (e.g., magnets used in pillows, mattress pads, back belts, knee braces, wrist bands, and insoles) may unintentionally cause the deep brain stimulation system to turn on or off.

Multiple leads. When multiple leads are implanted, route the lead extensions so the area between them is minimized. If the lead-extensions are routed in a loop, the loop will increase the potential for electromagnetic interference (EMI).

Abandoned leads, lead implant (replacement), and abandoned leads. The long-term safety associated with multiple implants, leads left in place without use, replacement of leads, multiple implants into the target structure, and lead explant is unknown.

Placement of lead/connection in neck. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture.

Long-term safety and effectiveness. The long-term safety and effectiveness of the Brio neurostimulation system has not been established beyond 5 years. Safety and effectiveness has not been established for patients with neurological disease other than Parkinson's disease or essential tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; patients under 22 years; implantation in targets other than STN for Parkinson's disease and VIM for essential tremor; patients with an active implantable device; patients requiring MRI.

Adverse Effects

Deep brain stimulation potentially has the following adverse effects:

Possible surgical complications. Surgical complications include, but are not limited to, the following: intracranial hemorrhage (which can lead to stroke, paralysis, or death); subcutaneous hemorrhage or seroma; hematoma; cerebrospinal fluid leakage or cerebrospinal fluid abnormality; brain contusion; infection or inflammation; antibiotic anaphylaxis; skin disorder; edema; persistent pain at surgery site or IPG site; erosion; brachial plexus injury (nerves to chest, shoulder and arm); postoperative pain, stress, or discomfort; neuropathy (nerve degeneration); hemiparesis (muscular weakness or partial paralysis on one side of body); ballism or hemiballism (uncontrollable movements on both or only one side of the body); confusion—transient, nocturnal or ongoing; cognitive impairment, including delirium, dementia, disorientation, psychosis and speech difficulties; aphasia; deep vein thrombosis; complications from anesthesia; phlebitis (vein inflammation); pulmonary embolism (sudden blood vessel obstruction); aborted procedures (air embolism, unable to find target, surgical complication, etc.); complications from unusual physiological variations in patients, including foreign body rejection phenomena; pneumonia, seizure or convulsions; paralysis (loss of motor function, inability to move); stroke and death.

Possible deep brain stimulation complications. Deep brain stimulation complications include, but are not limited to, the following:

- Device-related complications
  - Undesirable changes in stimulation related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections, or lead fracture
  - Loss of therapeutic benefit as a result of change in electrode positions, loose electrical connections, or lead or extension fracture
  - Initial jolt or tingling during stimulation; jolting or shocking sensations
  - Infection
  - Paresthesia
  - Lead fracture, migration, or dislodgement
  - Misplaced lead
  - Extension malfunction, fracture, or disconnect
  - Deep brain stimulation system failure or battery failure within the device
  - Deep brain stimulation system malfunction or dislodgement
  - Spontaneous turning on or off of the IPG
  - Allergic or rejection response to implanted materials
  - Persistent pain, tightness, or redness at the incision sites or general pain
  - General erosion or local skin erosion over the IPG
  - Persistent pain, tightness, or discomfort around the implanted parts (e.g., along the extension path in the neck)
  - Impaired wound healing (e.g., incision site drainage) or abscess formation
  - Additional neurosurgical procedure to manage one of the above complications or to replace a malfunctioning component
- Stimulation-related complications or other complications
  - Worsening of motor impairment and Parkinson's disease symptoms including dyskinesia, rigidity, akinesia or bradykinesia, myoclonus, motor fluctuations, abnormal gait or incoordination, ataxia, tremor, and dysphasia
  - Paresis, asthenia, hemiplegia, or hemiparesis
  - Dystonia
  - Sensory disturbance or impairment including neuropathy, neuralgia, sensory deficit, headache, and hearing and visual disturbance
  - Speech or language impairment including, aphasia, dysphagia, dysarthria, and hypophonia

- Cognitive impairment including attention deficit, confusion, disorientation, abnormal thinking, hallucinations, amnesia, delusions, dementia, inability to act or make decisions, psychic akinesia, long term memory impairment, psychiatric disturbances, depression, irritability or fatigue, mania or hypomania, psychosis, aggression, emotional lability, sleep disturbance, anxiety, apathy, drowsiness, alteration of mentation, postural instability and disequilibrium
- Restless leg syndrome
- Supranuclear gaze palsy
- Hypersexuality or increased libido
- Decreased therapeutic response
- Urinary incontinence or retention
- Diarrhea or constipation
- Cardiac dysfunction (e.g., hypotension, heart rate changes, or syncope)
- Difficulty breathing
- Increased salivation
- Weight gain or loss
- Eye disorder including eye apraxia or blepharospasm
- Nausea or vomiting
- Sweating
- Fever
- Hiccups
- Cough
- Cramps
- Worsening existing medical conditions

Patient Expectations

You and your doctor should discuss the benefits and risks of deep brain stimulation. The primary goal of deep brain stimulation for Parkinson's disease is to increase the amount of time that you are not bothered by dyskinesias, i.e. involuntary movements. The primary goal of deep brain stimulation for essential tremor (ET) is to reduce your tremor. In patients with Parkinson's disease or ET who achieve these improvements, deep brain stimulation may improve their quality of life and reduce the need for medications.

As with any surgery or therapy, deep brain stimulation has risks and complications. See the "Adverse Effects" (page 12) for a list of complications associated with deep brain stimulation. Most side effects of deep brain stimulation surgery are temporary and are resolved within the first few months. However, some complications can be more serious or permanent. In the event that side effects are intolerable or you are not satisfied with the therapy, the deep brain stimulation system can be turned off or usually it can be surgically removed. You also need to be aware that you cannot undergo diathermy procedures, electroshock therapy, transcranial magnetic stimulation or MRIs as discussed in “Contraindications” (page 3). Talk to your doctor about the risks associated with placement and use of a deep brain stimulation system.

Your deep brain stimulation team will work with you to adjust programming and medication (if appropriate) to find the best possible combination for your symptoms and lifestyle. Programming will be done using a device that can “talk” with your stimulator through your skin. During the programming session, the clinician will explore a range of stimulation variables to determine the optimal settings for you. You will likely need to visit your deep brain stimulation team a few times to optimize your settings. Some people notice benefits quickly, and others may need more time. While your clinician is determining your settings, you may experience some temporary sensations. These temporary sensations normally stop when the settings are changed or adjusted.

The months following your surgery can be exciting as you become familiar with your deep brain stimulation system. Your symptoms may significantly improve, and you may begin to return to some of the activities you enjoy. Talk to your deep brain stimulation team about these activities to ensure that they won’t damage your system.

About Your System

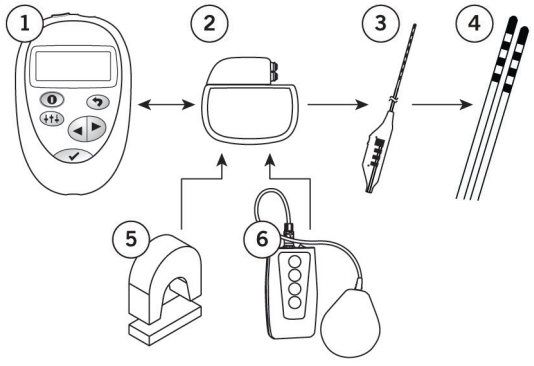
This neurostimulation system is a rechargeable system designed to deliver electrical stimulation to targets in the brain. The neurostimulation system includes the following primary components:

- Implantable pulse generator (IPG)
- Extensions
- Leads
- Patient programmer
- Patient magnet
- Charging system

The IPG connects to the implanted extensions, which connect to the leads implanted in the brain. The IPG delivers electrical pulses through the extensions and leads to electrodes at a selected target in the brain in order to provide therapeutic stimulation. The patient magnet can turn the IPG on and off. Clinicians use the patient programmer to create and modify a program for a patient. Patients use the patient programmer to control their prescribed program and the charging system to recharge their IPG's battery.

The following image shows how the major system components are intended to interact.

Figure 1. Interaction between major system components



1. Patient programmer
2. IPG
3. Extensions
4. Leads
5. Patient magnet
6. Charging system

About Your Programmer

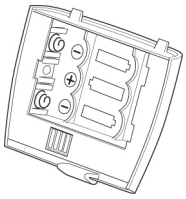
The patient programmer allows you to view, select, and control the programs, which your physician has prescribed. The programmer communicates with the IPG through a communication wand using radiofrequency (RF) signals.

Package Contents

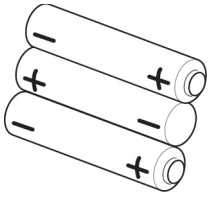
The Brio™ patient programmer package (Model 6860) includes the following items:

Patient programmer

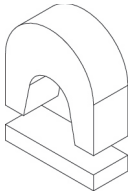
Communication wand



Battery pack



AAA batteries (3)



Patient magnet

Programmer case

Your Personal Identification Card

A personal medical identification card is included in the package of your programmer. This card does the following things:

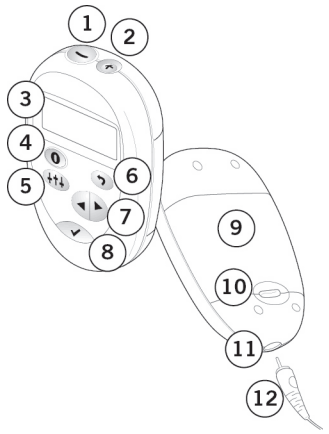
- Identifies you as having an implanted medical device
- Helps you pass through security systems like those in airports
- Provides information that allows your physician to be contacted in an emergency

If you have questions about your card, contact Customer Service.

Parts of the Patient Programmer

The following image shows the different parts of the patient programmer.

Figure 2. Parts of the Patient Programmer



1. Decrease key
2. Increase key
3. Display screen
4. Power key
5. Balance key
6. Previous Screen key
7. Scroll keys (left and right)
8. Select key
9. Battery pack
10. Battery release latch
11. Wand port
12. Communication wand connector

The following table provides descriptions of the functions of the programmer keys.

Table 1. Functions of the programmer keys

Key	Description	Function
	Decrease key	Decreases the amplitude of the program that is running.
	Increase key	Increases the amplitude of the program that is running.
	Power key	Turns on the power to the programmer and turns the IPG on and off. After one minute of inactivity, the programmer automatically shuts off.
	Balance key	Opens the Menu screen for changing user settings and viewing system information.
	Select key	Selects and activates menu changes. Confirms on-screen messages.
	Previous Screen key	Returns the display to the previous screen or cancels an action.
	Scroll keys	Scroll through menu options.

Setting Up the Patient Programmer

This section provides information about getting the patient programmer ready to control programs, changing the programmer settings, and viewing system information.

NOTE:

Each time before using the system, inspect the device and its accessories for damage. Avoid using a damaged device or accessory. Return it to St. Jude Medical for evaluation.

Turning the Programmer On and Off

To turn the programmer on, press the Power key.

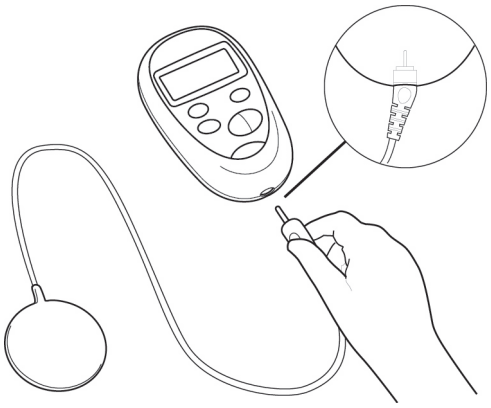
To turn the programmer off, do not press any keys for one minute. The programmer automatically turns off after one minute of inactivity.

Communicating With the IPG

To establish communication with the IPG, follow these steps:

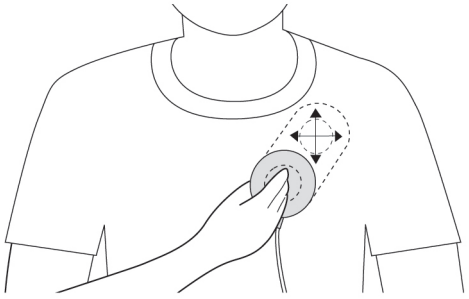
1. Ensure that the programmer is off. (It turns itself off after one minute of non-use.)
2. Plug the communication wand into the wand port on the bottom of the programmer.

Figure 3. Plug the wand into the programmer



3. Press the Power key to turn on the programmer. The Diagnostic Test screen appears.
4. Place the flat, circular end of the wand over the IPG site.

Figure 4. Place the wand over the IPG site



5. Wait for the LOCATING IPG screen to appear, and hold the wand in place. The programmer beeps while it is trying to locate the IPG.

Figure 5. LOCATING IPG screen

NOTE:

The programmer will try to locate the IPG for about 5 seconds before a screen appears to retry communication. If the programmer does not establish communication, move the wand slowly over the IPG site in small circular movements until you achieve communication.

NOTE:

After you have established communication with the IPG, keep the wand in place. If you move the wand from over the IPG site, you may lose communication with the IPG.

6. Check the programmer's screen to verify that the programmer has established communication with the IPG. When the programmer finds the IPG, the beeping stops and the following screen appears.

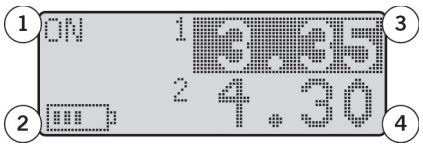
Figure 6. IPG FOUND screen

The next screen that appears shows information about the IPG, and then the Home screen appears. See "About the Home Screen" (page 21) for more information.

About the Home Screen

The Home screen is the main screen of the patient programmer. From this screen, you can view and control programs in the standard operating mode. The following image shows the main parts of the Home screen.

Figure 7. Parts of the Home screen



1. Stimulation status
2. IPG battery level
3. Amplitude of lead 1
4. Amplitude of lead 2

Stimulation status. Shows whether stimulation is on (ON), off (OFF), or ramping to the programmed amplitude level (RAMP).

IPG battery level icon. Shows how much power is left in the IPG battery. This icon is always displayed on the Home screen so you can easily check the status of the IPG battery.

Amplitude of lead 1. Shows the amplitude value (in mA) of lead 1. When stimulation is off, the amplitude value reads 0.00.

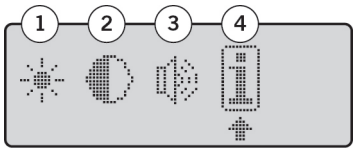
Amplitude of lead 2. Shows the amplitude value (in mA) of lead 2. When stimulation is off, the amplitude value reads 0.00. If only one lead is implanted, then this area on the screen is blank.

Changing Programmer Settings

You can change programmer display and volume settings from the Menu screen. Follow these steps:

1. From the Home screen, press the Balance key. The Menu screen appears.

Figure 8. The Menu screen



1. Backlighting icon
2. Contrast icon
3. Volume icon
4. Information icon

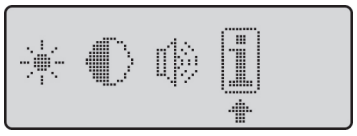
2. Press either Scroll key until the arrow is under the icon of the setting that you want to change: backlighting, contrast, or volume.
3. Press the Select key. The programmer displays the screen of the setting you selected.
4. Press the Scroll keys to adjust the selected setting.
5. To save your changes, press the Select key. The Home screen appears.

Displaying IPG and Programmer Information

You can view information about the IPG and the programmer from the Menu screen. Follow these steps:

1. From the Home screen, press the Balance key. The Menu screen appears.
2. Press either Scroll key until the arrow is under the Information icon.

Figure 9. Select the Information Icon



3. Press the Select key. A screen appears showing information about the programmer and its remaining battery power.

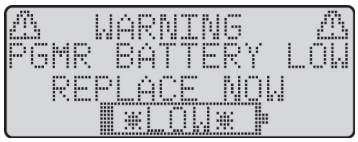
Figure 10. Programmer information screen

4. To view the screen showing IPG information, press the Scroll key on the right. To view the screen showing the programmer information again, press the Scroll key on the left.
5. When you are finished viewing the information screens, press the Select key.

Replacing the Programmer Batteries

The programmer is powered by three disposable AAA alkaline batteries contained in a battery pack. When the battery power is low, an alarm will sound and the following screen appears. If this occurs, you should replace your AAA batteries.

Figure 11. Programmer Battery Low screen



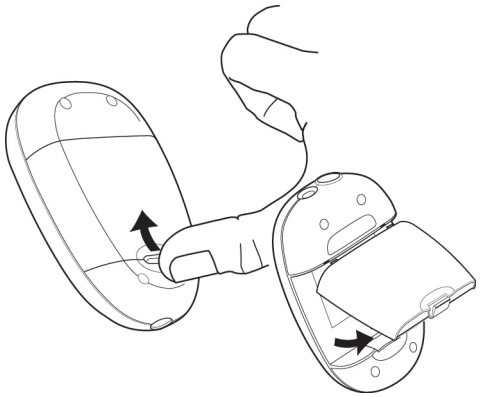
NOTE:

Do not dispose of batteries as general waste. Follow local regulations about disposing of batteries safely.

To replace the batteries in the programmer, follow these steps:

1. Ensure the programmer power is off.
2. Push and hold the battery release latch on the bottom of the battery pack, and lift the battery pack from the battery compartment.

Figure 12. Remove the battery pack from the programmer



3. Remove the AAA batteries from the battery pack, and insert new AAA batteries into the battery pack, ensuring that the + and - signs on the batteries line up with the signs in the battery pack.
4. Place the battery pack into the battery compartment.

Using the Programmer

This section provides information for using the programmer to select and control programs. Before you start these instructions, you need to establish communication with the IPG. See “Communicating With the IPG” (page 19).

Starting Stimulation

To start stimulation, follow these steps:

1. From the Home screen, press the Power key. While stimulation is starting and arriving at the target stimulation level, the stimulation status in the upper left corner of the Home screen changes to RAMP and an hourglass icon is displayed.

Figure 13. Stimulation ramping to the target amplitude level

2. After the stimulation status changes to ON, you can press the Increase key to increase the stimulation strength. To decrease the stimulation strength, press the Decrease key.

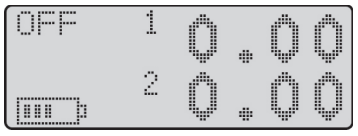
Stopping Stimulation

You can turn off the IPG and stop stimulation by using either the programmer or the magnet. With the magnet, you can stop stimulation immediately.

Stopping Stimulation Using the Programmer

To stop stimulation using the programmer, press the Power key. The programmer turns off the IPG and stimulation stops. You should see the following screen.

Figure 14. Home screen showing stimulation off



Stopping Stimulation Using the Magnet

The system comes with a magnet that can turn the IPG on and off.

NOTE:

If you hold the magnet over the IPG site for about 30 seconds, the IPG will turn off and you must use the programmer to turn it back on.

NOTE:

The magnet is powerful and intended for use solely with IPGs. When the magnet is not in use, position the keeper bar on it properly.

NOTE:

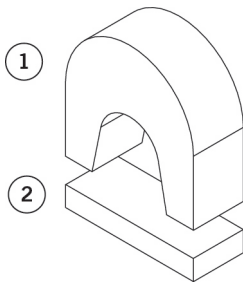
You can also start stimulation using the magnet by following the same steps for stopping stimulation.

CAUTION:
Do not use the magnet provided with system around magnetically sensitive items to avoid damaging them.

To stop stimulation using the magnet, follow these steps:

1. Take the keeper bar off the magnet.

Figure 15. Take the keeper bar off the magnet



1. Magnet
2. Keeper bar

2. Place the magnet directly over the IPG.
3. Hold the magnet in place for two seconds.
4. Remove the magnet, replace the keeper bar, and store the magnet.
5. If desired, confirm that stimulation is stopped by turning on the programmer and establishing communication with the IPG. In the Home screen that appears, OFF is displayed as the stimulation status in the upper left corner of the screen.

Recharging Your IPG

You may recharge your IPG on any schedule that is convenient for you and that maintains effective therapy. However, a daily recharge routine can reduce the time it takes to recharge the battery and can extend the life of your IPG.

For more information about when and how to recharge your IPG battery, see the user's guide for your charging system.

Checking the Remaining IPG Battery Capacity

You can check the level of your IPG battery on the bottom left corner of the Home screen.

Figure 16. IPG battery level icon

Caring for and Maintaining Your Programmer

To keep your programmer running its best, follow these guidelines:

- Handle the programmer with care. Avoid actions that may damage your programmer, such as dropping it on the floor.
- Keep your programmer and wand dry and avoid activities that might cause them to get wet.
- Clean your programmer and wand as needed by wiping the outer surface using a damp cloth and a small amount of mild soap. Do not submerge the programmer or wand in liquids or use a cloth that is soaked. Do not use alcohol, cleaning solutions, or solvents to clean the programmer or wand.
- To disconnect the wand from the programmer, do not pull on the cable. Gently pull from the connector that plugs into the programmer port.
- Do not expose the programmer to prolonged, direct sunlight.
- Use your programmer within a safe range of storage and operating conditions as shown in the following table.
- The expected service life of your programmer is 5 years. To order replacement parts for your system, contact Customer Service.

Table 2. Safe storage and operating conditions

Temperature	Storage	-10°C–55°C (14°F–131°F)
	Operating	10°C–40°C (50°F–104°F)
Relative humidity (noncondensing)	Storage	10%–90%
	Operating	30%–75%
Pressure	Storage	70–106 kPa (10.2–15.4 psi)
	Operating	70–106 kPa (10.2–15.4 psi)

Troubleshooting

This section provides troubleshooting procedures to help you identify and solve problems that may occur.

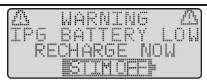
NOTE:

If problems occur other than those described in this section, contact Customer Service.

Troubleshooting a Diagnostic Message

The programmer contains an automatic diagnostic program that continuously checks the system during operation. If a malfunction or abnormal condition is detected related to the programmer, IPG, or wand, a diagnostic message will appear. The following table describes how to troubleshoot the common diagnostic messages.

Table 3. Troubleshooting for diagnostic messages

Programmer Message	Screen	Solution
Connect wand		Ensure the wand is properly connected to the programmer.
Diagnostic error		Call Customer Service.
Invalid program		Have your physician edit the program
IPG battery low (recharge battery)		Stimulation continues, but the IPG battery is low. Press the Select key and recharge your IPG battery at your earliest convenience (see the charging system user's guide).
IPG battery low (stim off)		Stimulation stops to preserve the low IPG battery. Press the Select key and recharge your IPG battery (see the charging system user's guide).
IPG communication error		Reposition the wand over the IPG and press the Select key.
IPG not found		Reposition the wand over the IPG and press the Select key.

Programmer Message	Screen	Solution
No program		Have your physician edit the program
Programmer battery low		Replace the batteries in the programmer.
System error		Contact Customer Service
Wrong IPG type		Contact Customer Service

Troubleshooting Other Potential Problems

Refer to the following table for possible causes and solutions to problems you may have.

Table 4. Possible causes and solutions to potential problems

Problem	Possible Cause	Possible Solution
Uncomfortable stimulation	Unintended programming change.	Decrease the amplitude. If you are unable to correct the problem, turn off the IPG and contact your physician.
No stimulation	Stimulation is off.	Start stimulation.
	IPG battery needs recharging.	Recharge your IPG battery. (See the charging system user's guide.)
	Unintended programming change.	Contact your physician.
	Implanted components are not functioning.	Contact your physician or Customer Service.
Intermittent stimulation	Implanted components are not functioning.	Contact your physician or Customer Service.
Ineffective stimulation	Lead position changed.	Adjust the amplitude. If you are unable to adjust stimulation satisfactorily, contact your physician.
	Programmer is damaged.	Contact Customer Service.

Problem	Possible Cause	Possible Solution
No control of the IPG	Wand is positioned incorrectly.	Reposition the wand over the IPG.
	Wand is not inserted properly.	Reinsert the wand.
	IPG is recharging.	Remove the charger antenna from over the IPG site, and use the programmer to try to communicate with the IPG.
	Electrical interference is interrupting communication between the programmer and the IPG.	Move to another area away from electrical equipment that can cause electrical interference, and try again.
	Wand is damaged.	Contact Customer Service.
	Programmer is damaged.	Contact Customer Service.
No programmer power or display	Programmer has not been used in over a minute and has automatically turned off.	Press the Power key.
	Batteries are depleted.	Replace the programmer batteries.
	Battery pack or batteries are not inserted properly.	Reinsert the battery pack or batteries.
	Programmer is damaged.	Contact Customer Service.

Service and Ordering Information

This section provides information for contacting Customer Service and for ordering replacement parts and accessories.

Customer Service Information

For help with a St. Jude Medical™ neuromodulation product, including technical service or repair, contact Customer Service using the following information:

St. Jude Medical
6901 Preston Road
Plano, TX 75024
USA

800 727 7846
972 309 8000
972 309 8150 Fax

Ordering Information

To order parts, contact Customer Service. Refer to the following list for order numbers.

Table 5. Ordering information for the patient programmer

Model	Description
1210	Patient magnet
1232	Communication wand
1254	Battery pack (light gray)
1272	Genesis programmer case*
6860	Patient programmer

*This accessory can be used with the Brio patient programmer (Model 6860).

Appendix A: Regulatory Statements

Please note the following regulatory statements related to the patient programmer.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Appendix B: Electromagnetic Compatibility Guidelines

The Brio™ patient programmer (Model 6860), hereafter the device, is medical equipment and should be used with the following guidance:

Guidance and Manufacturer's Declaration — Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy for its internal and system interface functions. 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 device 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

NOTE: The RF output frequency of the device is 50.5 kHz. The field strength is 22.5 dB•µA/m at 10 m (inductive couple device).

Guidance and Manufacturer's Declaration — Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	No guidance for battery-powered devices.
Surge IEC 61000-4-5	±1 kV line to neutral	Not applicable	No guidance for battery-powered devices.
Voltage dips, short interruptions IEC 61000-4-11	<5% U_T 40% U_T 70% U_T	Not applicable	No guidance for battery-powered devices.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration— Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.17\sqrt{P}$ $d=0.18\sqrt{P}$ 80 to 800 MHz $d=0.35\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). 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.[b]
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	20 V/m	

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

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 (mobile/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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b.] Over the frequency range 150 kHz and 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Device

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

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	80 to 800 MHz $d=0.18\sqrt{P}$	800 MHz to 2.5 GHz $d=0.35\sqrt{P}$
0.01	0.12	0.02	0.04
0.1	0.37	0.06	0.11
1	1.16	0.18	0.35
10	3.67	0.55	1.11
100	11.6	1.75	3.5

NOTE: Wireless communications equipment, such as wireless home network devices, mobile and cordless telephones, and walkie-talkies, can affect the device. Keep the device away from wireless communications equipment at least the distance d as listed in the 800 MHz to 2.5 GHz column in the above table.

NOTE: For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

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