Brio™

Deep Brain Stimulation System

Clinician's Manual

St. Jude Medical

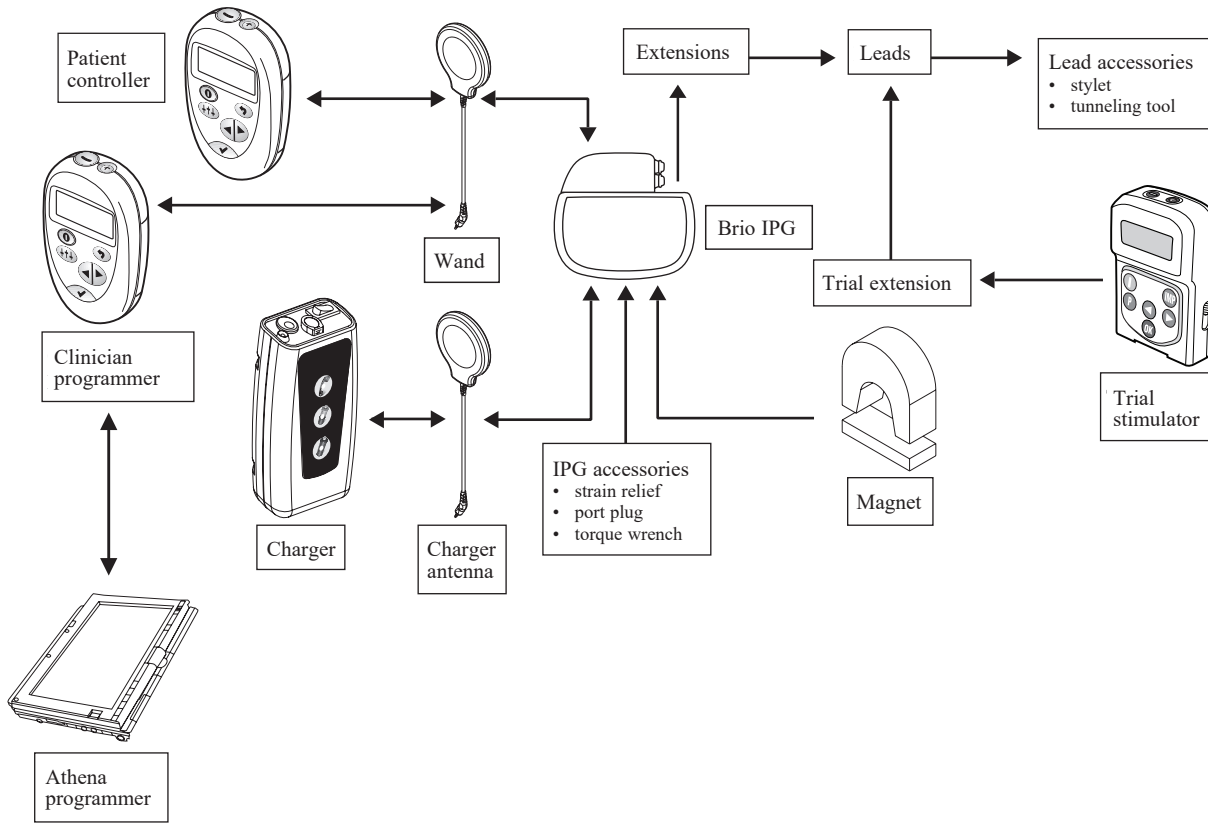
CONTENTS

ABOUT THIS MANUAL

This manual provides information about the St. Jude Medical™ Brio™ clinician programmer (Model 6851) and Brio™ implantable pulse generator (IPG, Model 6788). For information about other components of the Brio™ deep brain stimulation (DBS) system, see the manuals packaged with those products.

BRIEF SYSTEM DESCRIPTION

The Brio DBS system consists of an implantable neurostimulator, known as an IPG, which is used with leads and extensions of various lengths and is programmed by an external programmer. The IPG can also be controlled by a patient controller and is recharged by a portable charger. This system is designed to deliver electrical stimulation in various combinations of amplitude, pulse width, and frequency to specific targets in the brain. The IPG, leads, and extensions comprise the implantable components of the Brio DBS system. The Brio clinician programmer, the Athena™ programmer, the Brio™ patient controller, and the Brio™ LE charging system support the operation of the IPG.



SYMBOLS AND DEFINITIONS

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


Caution, consult accompanying documents


Consult this document for important safety-related information (this symbol is blue and white on the device)


Consult instructions for use

Follow instructions for use on this website


Device contains a type BF applied part to protect you from shock. The device is internally powered and is intended for continuous operation.


Keep dry


Single use only

Do not resterilize


Expiration date


Date of manufacture


Manufacturing facility


Temperature limits for storage conditions


Humidity limits


Pressure limits


Do not use if the product sterilization barrier or its packaging is compromised

Catalog number


Manufacturer


Contents quantity

Pulse generator

Programmer

Accessories

SN Serial number

LOT Batch code

℞ ONLY Prescription use only

STERILE EO Ethylene oxide gas sterilization

EC REP Authorized European representative

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.

Australian Sponsor Australian Sponsor

CE 0086 European conformity, affixed according to the relevant provisions of AIMD directive 90/385/EEC and RE directive 2014/53/EU Annex II. Hereby, St. Jude Medical declares that this device complies with the essential requirements and other relevant provisions of these directives.

The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.sjmglobal.com/euconformity.

C SP US This device is listed by the Canadian Standards Association (CSA) International as certified

ADDITIONAL SYMBOLS FOR PRODUCT LABELS

The following table shows additional symbols that may appear on the product label for parts related to this kit.

Torque Wrench	Torque Wrench
Eon™ **Port Plug**	Port Plug
Patient Magnet	Patient Magnet
Communication Wand	Communication Wand
Genesis™ **Battery pack for Programmer**	Battery pack for Programmer
Genesis™ **Programmer Case**	Programmer Case
Brio™ **IPG, 16-Channel Rechargeable**	IPG, 16-Channel Rechargeable
Brio™ **Clinician Programmer**	Clinician Programmer

DISPOSAL GUIDELINES FOR BATTERY-POWERED DEVICES

These devices contain a battery, and a label is affixed to the devices in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to St. Jude Medical at the end of its operating life.

INTENDED USE

The Brio™ neurostimulation system is intended to deliver low-intensity electrical impulses to specific targets in the brain via leads and associated extensions that are compatible with the Brio system. The Brio™ clinician programmer is intended to be used with Brio™ IPGs.

INDICATIONS FOR USE

This system is indicated for use in unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease.

CONTRAINDICATIONS

Implantation of a Brio™ DBS system is contraindicated for the following:

- Patients for whom test stimulation is unsuccessful.
- Patients who are unable to properly operate the system.
- Patients with demand-type cardiac pacemakers.

The following procedures are contraindicated for patients that have been implanted with this device:

- **Diathermy.** Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a DBS system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in a severe injury or death. Diathermy is further prohibited because it may also damage the DBS system components. This damage could result in loss of therapy, requiring additional surgery for system replacement. Injury or damage can occur during diathermy treatment whether the DBS system is turned on or off. All patients are advised to inform their healthcare professional that they should not be exposed to diathermy treatment.
- **Magnetic resonance imaging (MRI).** Do not use a full body radiofrequency (RF) coil or other extremity coils on patients implanted with a DBS system. Because energy from MRI can be transferred through the implanted system, the potential for heat generation at the location of the electrodes exists. This isolated temperature rise may cause tissue damage at the location of the implanted electrodes, possibly resulting in severe injury or death. Injury can occur during MRI treatment whether the DBS system is turned on or off. All patients are advised to inform their healthcare professional that they should not be exposed to MRI. In the instance that MRI must be performed, precisely follow the guidelines provided in the appendix of this manual.

WARNINGS

Other system components. Refer to the individual system component manuals for additional warnings and precautions related to those devices.

Poor surgical risk. DBS systems should not be implanted in patients who are poor surgical risks, or have multiple illnesses, or have active general infections.

Implanted defibrillators. DBS systems may adversely affect the programming of implanted cardioverter defibrillators.

Explosive or flammable gases. Do not use programming devices in an environment where explosive or flammable gas vapors are present. The operation of programming devices could cause these vapors to ignite resulting in severe burns, injury, or death.

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

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

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.

Case damage. If the IPG or the programmer case is pierced or ruptured, injury could result from exposure to the battery chemicals or sharp edges.

High charge density. A potential 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 less-than-optimal lead placement.

If the stimulation parameters exceed 30 $\mu C/cm^2$, a warning will appear on the clinician programmer. Parameter values exceeding this charge density 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.

Compatibility. All Brio devices should be used only with compatible St. Jude Medical system components.

Cremation. The IPG should be explanted prior to cremation. Always return explanted components to St. Jude Medical for safe disposal.

Anticoagulants. 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 less than 30 Hz may be programmed; however, these frequencies may cause tremor to be driven (i.e., occur at the same frequency as the programmed frequency). For this reason, programming at lower frequencies is not recommended.

PRECAUTIONS

General Precautions

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

Physician training. Clinicians should be familiar with DBS therapy and be experienced in the diagnosis and treatment of the indication for which the DBS components are being used.

Patient selection. It is extremely important to select patients appropriately for DBS.

Infection. It is important to follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Implantation of two IPGs. If two IPGs are implanted, ensure that at least 20 cm (8 in) separates the implanted IPGs to minimize the possibility of inadvertent misprogramming of the wrong IPG during the programming session. Verify programmed parameters in both devices at the end of each programming session.

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.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances or may render the patient incapable of controlling the stimulator. If unpleasant sensations occur, the device should be turned off immediately.

Handling, Implantation, Sterilization, Storage, and Explantation

Single-use device. The implanted components of the Brio™ DBS system are intended for a single use only. Do not resterilize or reimplant an explanted component for any reason.

Expiration date. Do not implant a system component if the use-before date has expired.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, mechanical force, bending, twisting, or the use of sharp instruments may damage and cause failure of the components.

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

Exposure to body fluids or saline. If the metal contacts on the proximal end of the lead or extension are exposed to body fluids or saline prior to connection, corrosion can occur. If exposure occurs, clean the metal contacts with sterile deionized water or sterile water (not saline) and dry completely prior to connection and implantation.

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

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.

Component disposal. The IPG contains a lithium ion battery as well as other potentially hazardous materials. Do not crush, puncture, or burn the IPG because explosion or fire may result.

If possible, return all explanted components to the U.S. representative for analysis and safe disposal. Refer to the Customer Service section of this manual for the mailing address. Dispose of any unreturned components according to local environmental regulations.

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 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 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 DBS system if used directly over the implanted device.

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

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

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted DBS system. Contact between an active electrode and an IPG, lead, or extension can damage the system or cause direct stimulation of the tissue at the electrode site and cause severe injury to the patient. If the use of electrocautery is necessary, turn the IPG off.

Psychotherapeutic procedures. The safety of psychotherapeutic procedures, such as electroshock therapy and transcranial magnetic stimulation, which use equipment that generates electromagnetic interference, has not been established.

Electrocardiograms. DBS stimulation pulses may be detected by electrocardiograms.

Home and Occupational Environments

Electromagnetic interference (EMI). Certain commercial electrical equipment (e.g., arc welders, induction furnaces, and resistance welders), communication equipment (e.g., microwave transmitters, linear power amplifiers, and high-power amateur transmitters), and high-voltage power lines may generate sufficient EMI to interfere with the DBS system operation if approached too closely.

Household appliances. Household appliances that contain magnets (e.g., refrigerators, freezers, stereo speakers, and some power tools) may unintentionally cause the DBS system to turn on or off.

Patient activities/environmental precautions. Patients should take reasonable care to avoid devices that generate strong EMI, which may cause unintended stimulation or the DBS 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.

Patient magnet. The magnet accessory available for the Brio™ DBS system is a high-powered magnet intended for use solely with the Brio system. The magnet must be kept away from watches, credit cards, computer disks, and other magnetically sensitive items to avoid damaging them. The “keeper bar” should be placed on the magnet when not in use.

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 DBS system to turn on or off.

Radiofrequency sources. Devices that contain permanent magnets (e.g., mobile telephones, cordless telephones, standard wired telephones, and AM/FM radios) may unintentionally cause the IPG to turn on or off.

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

GENERAL CARE

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

- Handle the programmer with care. It is a sensitive electronic device that can be damaged by rough handling (e.g., dropping it on the ground).
- The programmer is not waterproof; therefore, avoid activity that might cause it to get wet.
- Occasionally clean your programmer, and inspect it for damage before using it. Other than these activities, the programmer does not need any other routine maintenance, testing, or service.
- Clean the programmer whenever you want by wiping off the outer surface using a moist cloth and a small amount of mild soap. Do not submerge the programmer in liquids or use a cloth that has been saturated. Do not use alcohol, cleaning solutions, or solvents to clean the programmer.
- Do not expose the programmer to prolonged direct sunlight.

POSSIBLE ADVERSE EVENTS AND COMPLICATIONS

Implantation of a DBS system involves risk. In addition to those risks commonly associated with surgery, the following risks are associated with the implantation and/or use of this device:

Surgical complications. May occur, leading in some cases to surgical revision or explantation of the system. Surgical complications include, but are not limited to, the following:

- Intracranial hemorrhage (which can lead to paralysis or death)
- Subcutaneous hemorrhage or seroma, erosion, or infection
- Pain at the implant site
- Seizure or convulsions
- Aphasia and/or paralysis
- Stroke
- Bleeding
- Complications from anesthesia, including death
- Complications from unusual physiological variations in patients, including foreign body rejection phenomena
- Leakage of cerebrospinal fluid surrounding the brain

DBS complications. May occur, leading in some cases to surgical revision or explantation of the system. DBS complications include, but are not limited to, the following:

- Worsening of motor impairment and Parkinson's disease symptoms including rigidity, dyskinesia, worsening of motor fluctuations, tremor, abnormal gait or incoordination, akinesia or bradykinesia, dysphasia, and myoclonus
- Sensory disturbance or impairment including neuropathy, neuralgia, paresthesia, headache, and hearing and visual disturbance
- Paresis, asthenia, hemiplegia, or hemiparesis
- Cognitive impairment including confusion, abnormal thinking, hallucinations, alteration of mentation, amnesia, delusions, or dementia
- Anxiety
- Apathy
- Drowsiness
- Difficulty breathing
- Increased salivation
- Nausea and/or vomitting
- Rapid heart rate
- Pneumonia
- Skin disorder
- Syncope
- Edema
- Eye disorder
- Sweating
- Cerebrospinal fluid abnormality
- Disequilibrium
- Ataxia
- Dystonia
- Attention deficit
- Jolting or shocking sensations
- Speech or language impairment, dysarthria
- Sleep disturbance
- Psychiatric disturbances and depression
- Postoperative pain, stress, or discomfort
- Lead fracture, migration, or dislodgement
- DBS system failure or battery failure within the device
- DBS system dislodgement
- Undesirable changes in stimulation possibly related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections, and/or lead fracture
- Urinary incontinence
- Diarrhea
- Persistent pain at the IPG sites or general pain
- Allergic or rejection response to implanted materials
- General erosion or local skin erosion over the IPG
- Decreased therapeutic response
- Diminished, or loss of, Parkinson's symptoms relief

SYSTEM DESCRIPTION

A Brio™ DBS system consists of the following primary components: IPG (neurostimulator), leads and extensions, programmer, patient controller, and charging system. Please refer to the Brio system card enclosed with this product for a detailed list of components and their respective St. Jude Medical part numbers.

IPG

The Brio™ IPG is designed to be connected to one or two extensions. The IPG is powered by a hermetically sealed rechargeable battery within a titanium case and uses microelectronic circuitry to generate constant current electrical stimulation.

The IPG is conductive on all sides. This allows the IPG case to be used as an anode for monopolar stimulation. Ensure that the marked side is implanted facing up and away from muscle.

The IPG contains a radiopaque identification tag. The identification tag is visible inside the IPG header using standard X-ray procedures. The tag contains a code: “SJM” identifies St. Jude Medical as the manufacturer; “V” identifies the device as a Brio Model 6788; and the two numbers following the “V” denote the year of manufacture (see Figure 1).

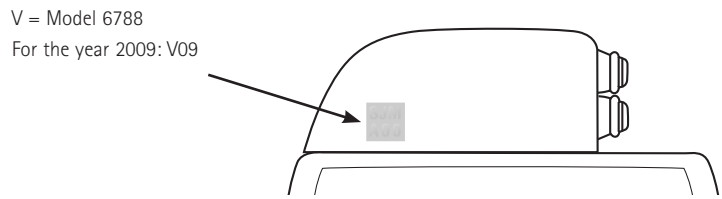


FIGURE 1

Leads and Extensions

St. Jude Medical DBS leads consist of electrodes on the distal end, connected by individually insulated wires to contact bands on the proximal end. The proximal end has a nonoperational metal band (the most distal band) that serves as an insertion handle. The insulated wires are covered by a biocompatible polymer. DBS leads are designed for introduction into the brain using standard stereotactic neurosurgical techniques.

The DBS extension is designed to connect the lead to the IPG. One end of the extension is designed to receive the proximal end of the lead, and the opposite end of the extension is designed for insertion and connection with the IPG.

Consult the manual packaged with the lead or extension for more information and directions for use of these devices.

Programmer

The clinician programmer is an external device that is used to program the stimulation parameters of Brio™ neurostimulators via RF telemetry.

Controller

The patient controller allows the patient to check the status of their Brio™ IPG, adjust its amplitude (optional), and turn it on or off. Consult the Brio™ patient controller user's guide for specific information related to the patient controller.

Charging System

The charging system provides the capability to recharge the IPG battery while stimulation is either on or off. The system consists of a charger, antenna, power adapter, and power cable. The charger transmits RF energy through the antenna to the IPG battery to recharge it.

For more information about the charging system, see the charging system user's guide.

Sterilization Information

Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the operative field. An expiration date (or "use-before" date) is marked on the label of each package.

CAUTION: St. Jude Medical implantable components are intended for single use only. Do not resterilize.

Product Materials

The products in this kit contain the following materials that are intended to come into contact with tissue:

- Polybutylene terephthalate (pocket sizer)
- Polysulfone
- Silicone rubber
- Titanium

SUGGESTED IMPLANT GUIDELINES

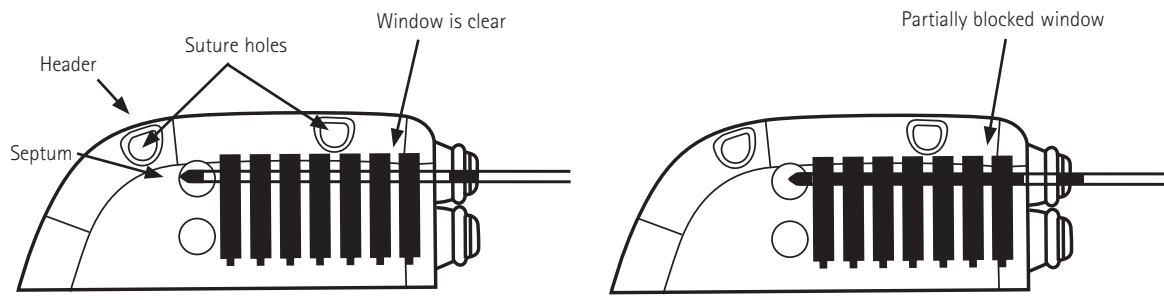
The implanting surgeon should carefully review the following suggested guidelines for implantation of the Brio™ IPG.

Connecting Extensions to the IPG

1. Before connecting extensions to the IPG, verify that the IPG is functional. This step is recommended to be performed while the IPG is still in the manufacturer's packaging. Connect the communication wand to the programmer, place the wand over the IPG, turn on the programmer, and verify communication with the IPG.
2. If needed, clean the proximal end of the extension with sterile, deionized or distilled water and dry it completely. Use clean gloves and ensure that all body fluids and saline residue are cleaned from the proximal end of the extension. This is important to reduce future corrosion and potential failure of the system.

CAUTION: Exposure of the internal IPG contacts to body fluid or saline can affect stimulation. If this occurs, clean the contacts with sterile, deionized or distilled water (not saline) and dry completely prior to extension connection and subsequent implantation.

3. Carefully slide the proximal end of the extension into the IPG header until it stops (see Figure 2).



Correct insertion

Incorrect insertion

FIGURE 2

4. Turn the torque wrench clockwise to tighten the setscrew until the torque wrench clicks (see Figure 3).

NOTE: After the torque wrench is removed, check the wrench access septum to ensure it has closed. If the septum is not closed, gently reseat the septum flaps.

CAUTION: Use only the torque wrench included in the extension, IPG, or torque wrench kit. If you need to loosen the setscrew, turn the setscrew (in quarter turns counterclockwise) just enough to insert or remove the extension from the IPG connector assembly. Loosening the setscrew too far will cause it to fall out.

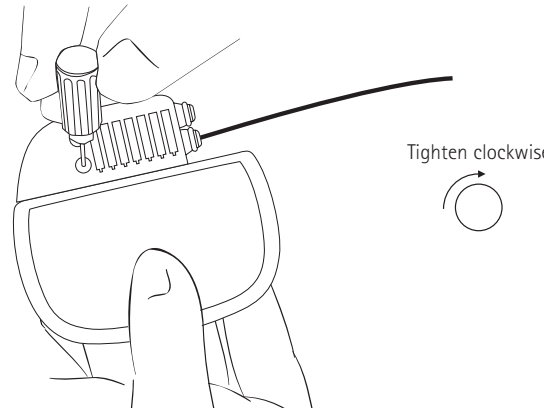


FIGURE 3

5. Repeat steps 2-4 for the other extension.

NOTE: In case only one extension is used with the Brio IPG, insert a Brio-compatible port plug into the unused IPG port.

Placing the IPG

1. Insert the pocket sizer in the IPG pocket to ensure that it is large enough to accommodate the IPG and the excess extension length. Remove and discard the pocket sizer when finished.

CAUTION: The pocket sizer is not intended for permanent, long-term implantation.

2. Carefully place the IPG into the pocket, at a depth not to exceed 2.25 cm (0.9 in), with the logo side facing toward the skin surface.

CAUTION: Placing the IPG deeper than 2.25 cm (0.9 in) can impede or prohibit IPG communications with the clinician programmer and the patient controller, or prevent charging with the charging system.

3. Carefully coil any excess extension in loops no smaller than 2.5 cm (1 in) in diameter and place them behind the IPG (see Figure 4).

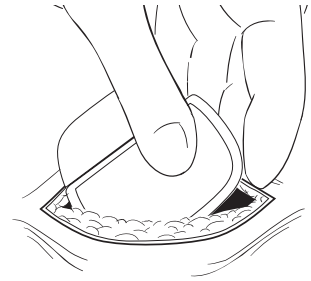


FIGURE 4

4. To stabilize the IPG within the pocket and minimize movement, pass a suture through a suture hole at the top of the IPG header (see Figure 2) and secure it to the connective tissue.

5. Before closing, verify that the system is operational by placing the wand from the Brio™ clinician programmer in a sterile bag, positioning the wand over the IPG, and turning the programmer on.

NOTE: If a communication error occurs during programming, try to reposition the wand over the IPG. If the problem persists, refer to the "Troubleshooting" section of this manual.

6. Close the IPG pocket incision. The IPG should be positioned away from the pocket incision suture line (see Figure 5).

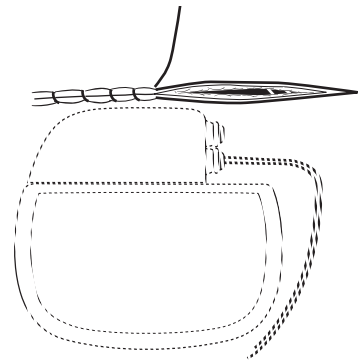


FIGURE 5

CAUTION: Exercise caution not to puncture the IPG header or extensions while closing the incision.

WARNING: Do not use surgical staples to close the IPG pocket; use suture. Using surgical staples can cause tissue damage during charging, and may interfere with IPG communication to the programmer and the controller.

7. Complete the patient registration information and identification card, and give the identification card to the patient.

Replacing the IPG

1. After ensuring that the IPG is turned off, open the IPG pocket per normal surgical procedure, and carefully remove the IPG from the pocket.

CAUTION: Exercise extreme caution when using sharp instruments and electrocautery around the extension.

2. Insert the torque wrench into the IPG header septum and loosen the setscrew by turning it counterclockwise.

3. Gently pull the extension from the IPG header. Clean and dry all contacts on the extensions, ensuring they are free of fluid and tissue.

NOTE: If an extension needs to be replaced, do the following:

i. Make an incision above the extension connector assembly and disconnect the extension from the lead.

ii. Sever the distal end of the extension just proximal to the extension connector assembly.

iii. Carefully pull the extension out through the IPG pocket.

iv. Place the new extension following the procedure specified in the extension packaging.

4. Insert the extension into the new IPG.

5. Tighten the setscrew clockwise until the torque wrench clicks.

6. Remove the torque wrench and ensure the septum is closed.

7. Repeat steps 1-7 in the “Placing the IPG” section of this manual.

8. Return any explanted components to St. Jude Medical. Refer to “Explanted Component Disposal” for more information.

EXPLANTED COMPONENT DISPOSAL

Explanted components should be returned to St. Jude Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your St. Jude Medical representative or Customer Service.

CLINICIAN PROGRAMMER

Overview

The Brio™ clinician programmer is an external device that is used to program the stimulation parameters of Brio™ neurostimulators via RF telemetry. The major parts of the clinician programmer are shown in the following illustration.

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.

The general flow of the programmer operation is as follows:

- The programmer provides a series of menu choices arranged in a continuous loop. There are two types of choices: parameters (which have a value that can be adjusted) and actions (which cause an action to occur).
- The and buttons are used to move forward and backward between the choices.
- The and buttons are used to change the value of the highlighted choice.
- The button is used to initiate or select the highlighted choice.
- The power button is used to turn the programmer on and off and also to turn stimulation off when in the programming mode.
- The button is used only in the PREF menu.
- The button is not used.

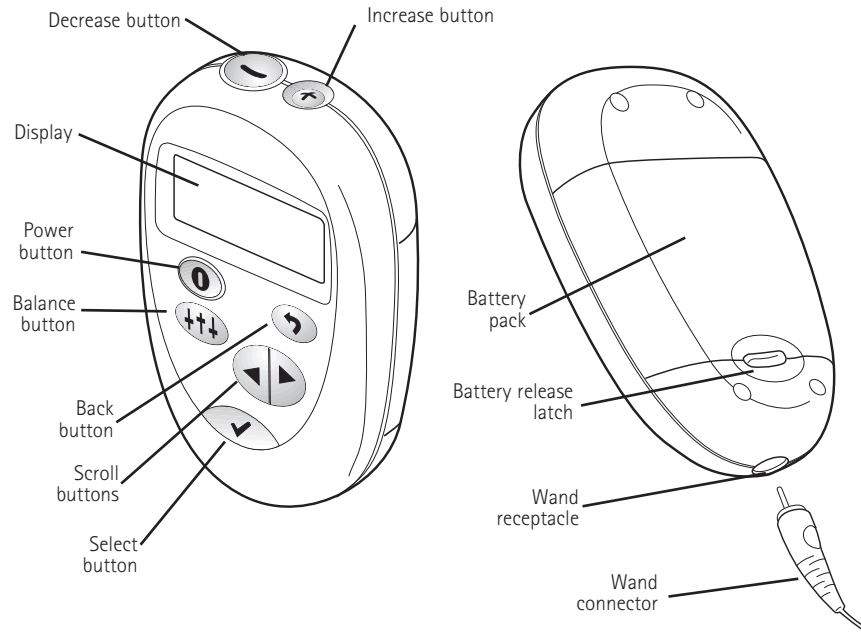


FIGURE 6

Demo Mode

A demo mode is available in the clinician programmer. Demo mode is intended as a training tool to practice using the programmer prior to using it during an actual programming session. All of the major functions of the programmer are simulated in demo mode.

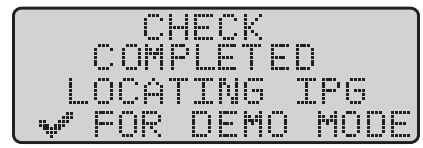
Entering Demo Mode

With the programmer off

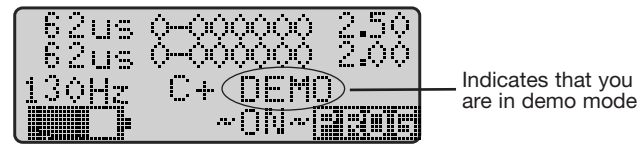
1. Place the communication wand at least 20 cm (8 in) away from all neurostimulators, computers, or sources of electromagnetic interference.

2. Press the power button to turn the programmer on.

3. Press the green button when the following screen appears.



4. The Home screen (see the following image) will appear when you have entered demo mode. Follow the directions in the "Understanding the Home Screen" section of this manual to enter programming mode, and the directions in the "Programming Mode" section to practice programming.



Exiting Demo Mode

1. Return to the Home screen by

   - using the scroll buttons to highlight EXIT then pressing the green button.
   - then highlighting SAVE AND EXIT and pressing the green button.

2. From the Home screen, press the button to turn the programmer off.

Basic Operation and the Home Screen

This section provides an overview of the most commonly used features of the programmer. See the "Programming Mode" section of this manual for instructions on programming the IPG.

Turning the Programmer On

To turn on the programmer and establish communication with the IPG, follow these steps:

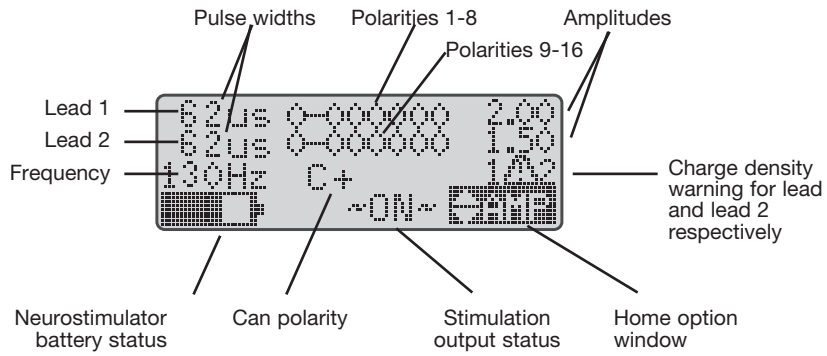
1. Ensure the wand connector is fully inserted in the wand receptacle on the bottom of the programmer.
2. Press the power button.
3. Place the wand over the neurostimulator.
4. Wait for the Home screen to appear.

First, the programmer will run a series of self-tests. These tests take approximately 5 seconds and are designed to ensure that the programmer is functioning properly. No buttons on the programmer are operational during the self-tests except the power button that can be used to turn the programmer off. Next, the programmer automatically attempts to establish communication with the neurostimulator. If it is able to establish communication, it will display the Home screen.

NOTE: The programmer beeps to indicate that it is communicating with the IPG. As necessary, reposition the programmer over the IPG to establish and maintain the communication link.

Understanding the Home Screen

The Home screen is displayed whenever the programmer is turned on and has successfully established communication with the neurostimulator. This screen provides a summary of the stimulation parameters, lead polarities, stimulation output (on/off) status, and neurostimulator battery status. The screen also includes a Home option window for access to the programmer functionality.



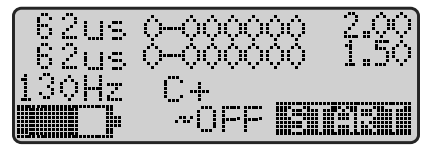
Brio Home screen

Use the scroll buttons to change the function displayed in the Home option window in the lower right corner, then use the green button to select that action. The Home option window choices are shown below. The programmer hides (does not offer) choices that are incompatible with the current stimulation program and neurostimulator status. The choices are arranged in a loop, so that, continuing to scroll in the same direction will ultimately bring you back to the first choice.

- START — Turns stimulation on (only available if stimulation is off)
- STOP — Turns stimulation off (only available if stimulation is on)
- PROG — Enters the programming mode
- AMP — Enters amplitude adjustment mode (only available if amplitude limits have been set)
- PREF — Provides access to programmer preferences

Turning Stimulation On

1. On the Home screen use the scroll button to highlight START in the lower right corner.

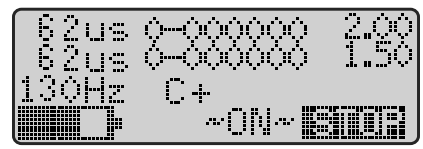


NOTE: The START option will not appear if the programmer detects a problem with the stimulation program. Instead, the programmer will offer the PROG option, so that the problem can be fixed by reprogramming the neurostimulator.

2. Press the green button. The stimulation output indicator will change from ~OFF to ~ON~, and the RAMP symbol will flash as stimulation increases from zero to the programmed amplitude. Keep the antenna over the IPG until PROG appears in the lower right corner.

Turning Stimulation Off

1. On the Home screen use the scroll button to highlight STOP in the lower right corner.

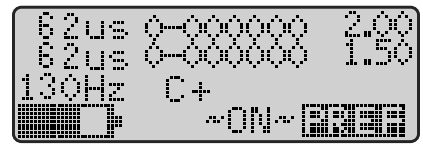


2. Press the green button. The stimulation output indicator will change from ~ON~ to ~OFF. Keep the antenna over the IPG until START appears in the lower right corner.

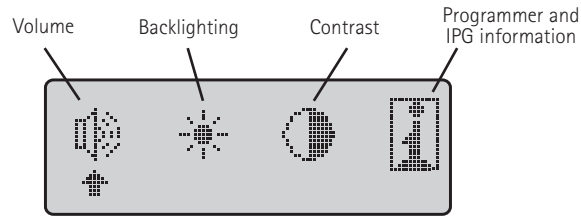
Setting Programmer Preferences

Use the PREF menu to adjust the volume, backlighting, or contrast of the programmer, or view programmer and IPG information.

1. On the Home screen use the scroll buttons to highlight PREF in the lower right corner.



2. Press the green button. The following screen will be displayed.

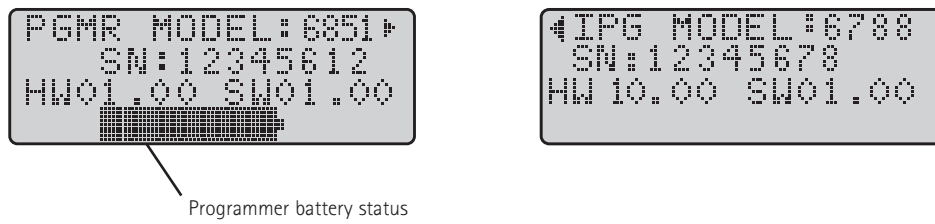


3. Use the scroll buttons to move the pointer arrow under the desired action, then press the green button. For example, to adjust volume move the pointer under the left-most icon and press .

4. Use the scroll buttons to adjust the preference setting.

5. When finished, press the green button to save the setting, or to leave the setting unchanged.

Selecting provides information about the programmer and the IPG as shown in the following image. Use the scroll button to move between the two screens, and the button to return to the preferences menu.



NOTE: The programmer information screen displays the status of your programmer battery. When the battery level is low, the word LOW will be displayed over the battery image. See the “Troubleshooting” section of this manual for instructions on replacing these batteries.

Using Amplitude Adjustment Mode

Amplitude adjustment mode is accessible from the Home screen when amplitude limits have been enabled. See “SET AMP LIMITS” for information on enabling amplitude adjustment mode. See the “Understanding the Home Screen” section for information on accessing amplitude adjustment mode.

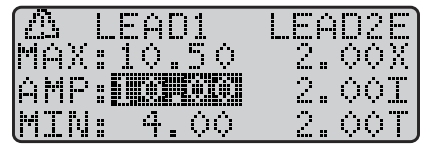
In this mode, the ⊕ and ⊖ buttons can be used to adjust stimulation amplitude in the same way that a patient would with a Brio™ patient controller.

Highlighting an AMP value and pressing:

⊕ increases stimulation amplitude by an amount equal to STEP

⊖ decreases stimulation amplitude by an amount equal to STEP

Highlighting EXIT and pressing ✔ returns to the Home screen.

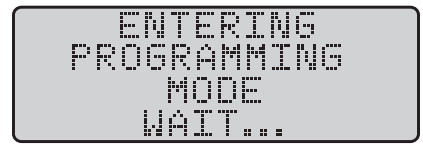


NOTE: The ⚠ on this screen indicates that the charge density limit is being exceeded.

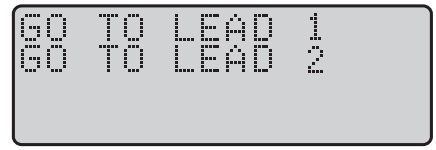
Programming Mode

Programming mode is used to change the parameters of the stimulation program and to interrogate the neurostimulator for certain diagnostic information. Programming mode provides a series of choices (parameters and actions) arranged in a loop that spans multiple screens. The scroll ◄► buttons are used to move forward (right) and backward (left) between the choices. Scrolling forward is used to move down the menu and over to the next screen forward. Scrolling backward is used to move up the menu and over to the previous screen.

To enter programming mode, proceed as follows from the Home screen. Select PROG in the Home option window and press ✔. The following screen will be displayed when entering the programming mode. Note that when entering programming mode, stimulation is briefly turned off and then ramped up back to the target level based on the RAMP settings of the current program. The following screen will be displayed until ramping is complete:

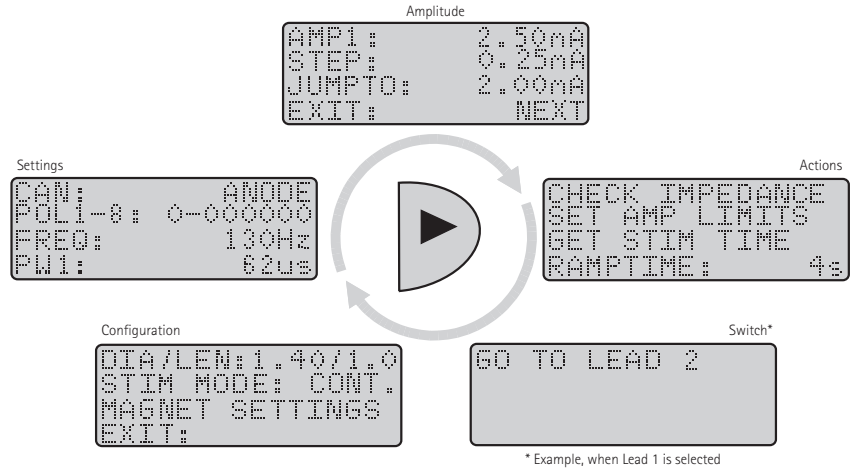


When in the programming mode, select between GO TO LEAD 1 or GO TO LEAD 2 to start programming. The following selection menu will be displayed:

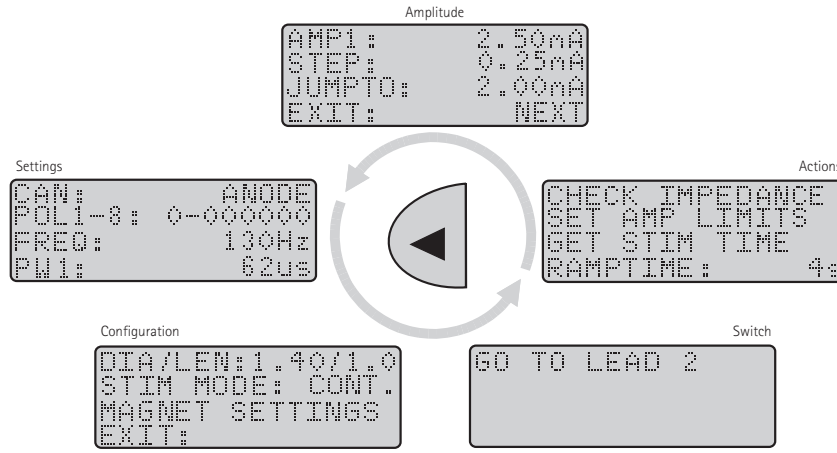


The sequence of menu selections in the programming mode is shown in the following diagrams (sample program screens are used).

Right scroll button cycle



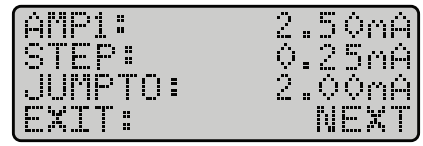
Left scroll button cycle



There are two types of choices in programming mode: actions and parameters. The following pages provide a description of the action and parameter choices available within programming mode.

Amplitude Menu

The amplitude menu contains four options: AMP, STEP, JUMPTO, and EXIT (see the following image). Each of these options is described in the following subsections.



AMP

Use this option to set the amplitude of the stimulation generated by the neurostimulator.

NOTE: When programming lead 1 (electrodes 1-8), the amplitude line will read AMP1. When programming lead 2 (electrodes 9-16), the amplitude line will read AMP2.

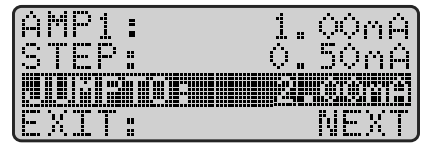
Highlighting this line and pressing:

⊕ increases AMP by an amount equal to STEP

⊖ decreases AMP by an amount equal to STEP

This line shows the amplitude of the stimulation being generated by the neurostimulator, and allows it to be changed. When AMP is zero, it will display OFF. Stimulation amplitude can be adjusted in the following ways:

- Highlight the AMP line and press ⊕ or ⊖ to increase or decrease amplitude by an amount equal to STEP
- Press the ⓪ button to turn amplitude off on both leads.
- Highlight JUMPTO, and then press ✔ to change amplitude to the value shown on the JUMPTO line.



NOTE: The ⚠ on the AMP or PW lines means that the charge density is above 30 µC/cm² at the current AMP and PW settings.

WARNING: A potential risk of tissue damage exists with stimulation parameter settings of high amplitudes and wide pulse widths. High amplitude and pulse width settings required to achieve therapy may indicate a system problem or suboptimal lead placement.

NOTE: When delivering stimulation from only one lead, set all electrodes on the other lead to zero.

STEP

Use this option to set the increment by which AMP will be adjusted both in programming mode, and in amplitude adjustment mode.

Highlighting this line and pressing:

 increases STEP by 0.05 mA

 decreases STEP by 0.05 mA

This line shows the increment by which the stimulation amplitude will be increased or decreased when the AMP line is highlighted and the  or  button is pressed. This allows you to change how stimulation is stepped up or down. A larger step size can be used to quickly make large amplitude changes, and a smaller step size allows fine tuning of the amplitude.

This parameter is also used to set the increment by which amplitude will be increased or decreased when using amplitude limits. Keep in mind the following points when using STEP for amplitude limits:

- STEP can be increased to reduce the number of amplitude steps offered to a patient.
- The STEP value for lead 1 can be different than the STEP value for lead 2.

JUMPTO

Use this option to immediately turn stimulation on to the amplitude value shown on this line.

Highlighting this line and pressing:

 immediately changes AMP to the amplitude displayed on the JUMPTO line

JUMPTO provides an alternate, shortcut method of adjusting the stimulation amplitude. Some of the uses for this feature may include:

- The JUMPTO line displays the value that the stimulation amplitude was at when the programming session was started, thereby providing a continuous reminder of the last programmed stimulation amplitude.
- The JUMPTO line also retains the current amplitude value at any time stimulation is turned off during programming, and therefore provides a fast way to turn stimulation back on.

CAUTION: Some patients may be startled by abruptly turning on stimulation. Use the AMP line to gradually turn on stimulation in patients who are sensitive to abruptly turning on stimulation.

EXIT

Use this option to exit programming mode and return to the Home screen.

Highlighting the EXIT line on either the Amplitude or Configuration screen and pressing:

 exits programming mode and provides the choice of saving or discarding the changes made to the program or returning to programming mode.

The following screen will be displayed:

- GO BACK option allows going back to programming without saving the changes made to the programming parameters.
- SAVE AND EXIT option allows saving the new program, exiting programming mode, and returning to the Home screen.
- DISCARD CHANGES option allows exiting programming mode and returning to the Home screen without saving any changes that were made during the programming session.

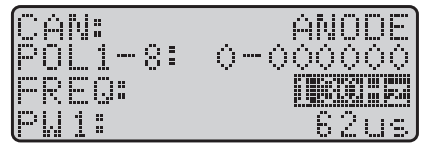
NOTE: After programming is complete, you must select EXIT to leave programming mode. The programmer will not turn off without exiting the programming mode, and it will periodically beep to remind you to EXIT programming mode.

NOTE: When exiting programming mode and while the stimulation is ramping to the target amplitude, no buttons on the programmer are operational.

CAUTION: Always exit programming mode, turn the programmer off, then back on before attempting to program a different IPG. Failing to do so, can abruptly change stimulation parameters in the second IPG.

Settings Menu

The settings menu contains four options: CAN, POL, FREQ, and PW (see the following image). Each of these is described in the following subsections.



CAN

Use this option to set the polarity of the neurostimulator case (CAN).

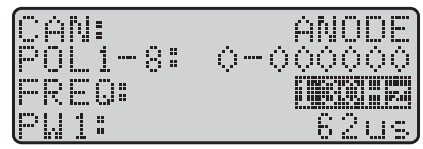
Highlighting this line and pressing:

⊕ toggles the can polarity between ANODE and OFF

⊖ toggles the can polarity between ANODE and OFF

The neurostimulator case can be programmed to be either: ANODE (a positive electrode, for monopolar stimulation), or OFF (not part of the stimulation circuit, for bipolar stimulation). Keep in mind the following when adjusting CAN:

- AMP will be turned off on both leads whenever CAN polarity is changed
- AMP limits will be disabled whenever CAN polarity is changed
- When CAN is set to ANODE, none of the electrodes on the lead can be set to anode (+). When CAN is changed to ANODE all electrodes set to anode will be automatically switched OFF (0).



NOTE: Both leads must have the same can setting. Therefore, changing polarity of the can when programming one lead will automatically change polarities of the can and electrodes as applicable on the other lead.

POL

Use this option to set the polarity of the electrodes on the lead.

Highlighting this line and pressing:

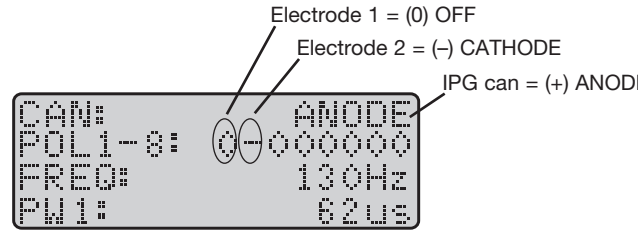
⊕ when CAN is OFF, cycles the polarity of the electrode from 0 (OFF) to + (anode) to – (cathode) to 0 (OFF)

⊕ when CAN is ANODE, cycles the polarity of the electrode from 0 (OFF) to – (cathode) to 0 (OFF)

⊖ when CAN is OFF, cycles the polarity of the electrode from 0 (OFF) to – (cathode) to + (anode) to 0 (OFF)

⊖ when CAN is ANODE, cycles the polarity of the electrode from 0 (OFF) to – (cathode) to 0 (OFF)

The programmer supports programming one or two leads with up to 8 electrodes per lead. The electrodes on lead 1 are numbered 1 through 8, with the most distal electrode designated electrode 1. Similarly, the electrodes on lead 2 are numbered 9 through 16, with the most distal electrode designated electrode 9. Electrode polarities are indicated as follows:



NOTE: Changing polarities of the electrodes will reset amplitude adjustment limits to zero. If desired, set new amplitude adjustment limits using the SET AMP LIMITS action.

NOTE: When delivering stimulation from only one lead, set all electrodes on the other lead to zero.

FREQ

Use this option to set the stimulation frequency.

Highlighting this line and pressing:

- (+) increases the stimulation frequency in increments of 10 Hz
- (–) decreases the stimulation frequency in increments of 2 Hz

This line shows the frequency of the stimulation currently being generated by the neurostimulator, and allows it to be changed. FREQ (frequency) is the number of stimulation pulses delivered each second.

NOTE: FREQ can be changed when programming either of the leads. However, both leads must have the same FREQ setting. When programming one lead, adjusting the frequency value will also adjust the frequency value for the other lead.

PW

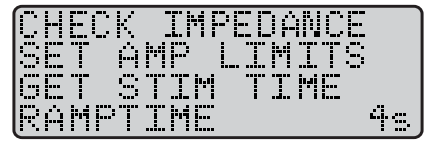
Use this option to set the pulse width of the stimulation produced by the neurostimulator.

Highlighting this line and pressing:

- (+) increases the width of the stimulation pulse by 12 or 13 microseconds (alternating)
- (–) decreases the width of the stimulation pulse by 12 or 13 microseconds (alternating)

Actions Menu

The action menu contains four options: CHECK IMPEDANCE, SET AMP LIMITS, GET STIM TIME, and RAMPTIME (see the following image). Each of these options is described in the following subsections.



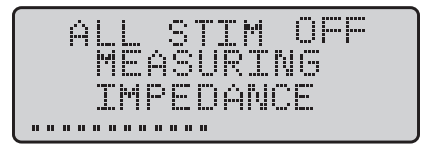
CHECK IMPEDANCE

Use this option to obtain the impedance of the lead with the current electrode configuration.

Highlighting this line and pressing:

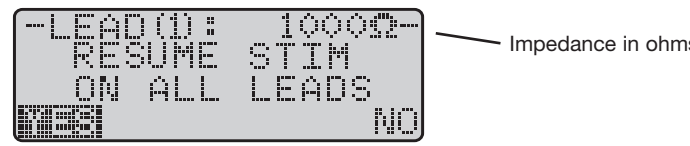
 starts the impedance measurement sequence.

The first step in the impedance measurement sequence is to turn stimulation off and display the following screen.

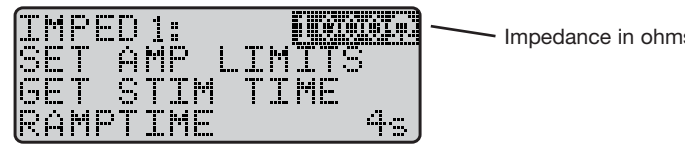


The impedance measurement takes a few seconds, and progress is indicated by the progress bar on the bottom of the screen. Keep the communication wand over the neurostimulator throughout the measurement.

After the measurement is taken, and if stimulation was on when the impedance measurement was requested, the result is presented along with a choice of resuming stimulation or not. If stimulation was not on when the impedance measurement was requested, then this screen will not be displayed.



After making the ramping choice, the impedance value will be displayed on the impedance line of the menu as shown in the following image.



NOTE: If the measured impedance is less than 200 ohms, it will be reported as LOW; and if it is more than 3,000 ohms, it will be reported as HIGH. If that happens, troubleshoot the system as this can be an indication of a short or open circuit respectively. If the impedance measurement times out before obtaining a value, the impedance line will display RETRY.

SET AMP LIMITS

Use this option to enable and set the values of the amplitude limits or to disable amplitude limits.

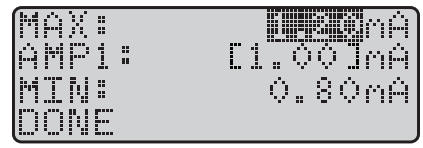
Highlighting this line and pressing:

 enters the amplitude limits configuration screen

The Brio™ neurostimulation system gives you the ability to allow your patients to adjust their stimulation amplitude using their controller within the limits that you prescribe. This feature is enabled from the amplitude limits configuration screen by changing MIN or MAX so that they are not equal to AMP. Amplitude limits are disabled by setting MIN and MAX equal to AMP. When finished, highlight DONE and press  to exit the amplitude limits configuration screen.

- MAX is the maximum amplitude to which patients will be able to increase their stimulation amplitude.
- MIN is the minimum amplitude (other than off) to which patients will be able to decrease their stimulation amplitude.
- STEP is the increment by which stimulation amplitude will be adjusted each time the increase amplitude or decrease amplitude button is pressed.

NOTE: Set STEP in the Amplitude menu before entering the amplitude limits configuration screen. Adjusting STEP afterward may cause MIN and/or MAX to reset.



Each time the increase amplitude or decrease amplitude button is pressed, stimulation amplitude is adjusted by an amount equal to STEP. This allows you to control both the range (from MIN to MAX) and the number of amplitude choices that you prescribe. Some patients may find it easier to have only a few choices, whereas others may need the fine-tuning that can be provided with more, but smaller, increments.

NOTE: Set amplitude limits just prior to exiting programming mode. Adjusting STEP or AMP afterwards may cause MIN and/or MAX to reset. Upon exiting programming mode, the programmer will automatically prompt you to change MIN if it is no longer less than or equal to AMP, or MAX if it is no longer greater than or equal to AMP.

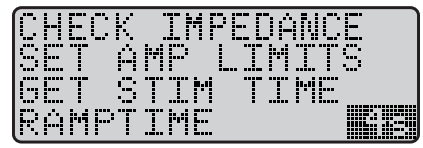
RAMPTIME

Use this option to set how long it will take to ramp stimulation up to the programmed amplitude when the neurostimulator is turned on.

Highlighting this line and pressing:

⊕ moves to the next longer ramp time

⊖ moves to the next shorter ramp time



Some patients may find it more comfortable to have stimulation gradually ramp up when the neurostimulator is turned on, rather than jumping directly to the programmed amplitude. The ramp time choices are 0, 2, 4, 8, 15, 30, 45, and 60 seconds.

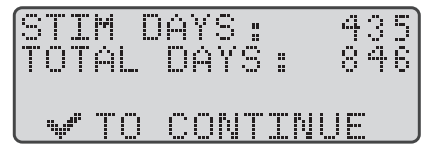
NOTE: RAMPTIME is also used to resume stimulation upon entry into programming mode and to resume stimulation after measuring impedance.

GET STIM TIME

Use this to get information about stimulator use.

Highlighting this line and pressing:

✔ reports the current values of TOTAL DAYS and STIM DAYS



TOTAL DAYS is the number of days since the neurostimulator was manufactured—whether or not stimulation output has been on.

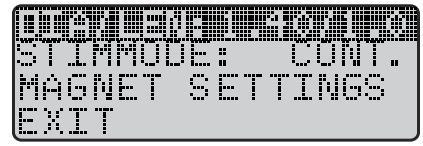
STIM DAYS is the number of days that stimulation was actually turned on.

NOTE: STIM DAYS is meant to count and report the cumulative time stimulation has been on, while TOTAL DAYS reports the number of calendar days that have elapsed since the IPG was manufactured. Therefore, as an example, if stimulation was on for 12 hours per day over a two-day period, STIM DAYS number will increment one day (24 hours cumulatively), while TOTAL DAYS will increment two days.

STIM DAYS and TOTAL DAYS can be useful for troubleshooting and assessing patient compliance. See the "Troubleshooting" section of this manual for details.

Configuration Menu

The configuration menu contains four options: DIA/LEN, STIMMODE, MAGNET SETTINGS, and EXIT (see the following image). Each of these options is described in the following subsections.



DIA/LEN (ELECTRODE DIAMETER AND LENGTH)

Use this to specify the dimensions (diameter and length in mm) of the electrodes on the lead being used.

Highlighting this line and pressing:

⊕ moves between the electrode diameter and length choices

⊖ moves between the electrode diameter and length choices

The programmer uses the electrode dimensions to calculate the average charge density and displays a warning when it exceeds 30 µC/cm^2. St. Jude Medical recommends that charge density not be exceeded. Each time the programmer is turned on, it resets this parameter to the smallest electrode dimensions. See the manual packaged with the DBS lead to determine the lead dimensions.

NOTE: This parameter is individually set for each lead.

STIMMODE

Use this option to set the stimulation mode.

Highlighting this line and pressing:

✓ enters the stimulation mode adjustment screen

The neurostimulator has two stimulation modes: continuous and cycle.

- Continuous mode produces stimulation until the neurostimulator is turned off via a magnet (if magnet mode is enabled), clinician programmer, or patient controller.
- Cycle mode produces stimulation in a repeating cycle of a defined “on” time followed by a defined “off” time. The Home screen will display a “C” in the lower left corner when the neurostimulator is in cycle mode.

After entering the stimulation mode adjustment screen, use the ⊕ / ⊖ buttons to toggle between CONT (continuous) and CYCLE modes. When CYCLE is selected use the scroll buttons and ⊕ / ⊖ buttons to adjust the H (hours), M (minutes), and S (seconds) for the cycle on and cycle off times in the stimulation mode adjustment screen. When finished, highlight DONE and press ✓ to leave the stimulation mode adjustment screen.

MAGNET SETTINGS

Use this option to set how the neurostimulator will respond if it senses a magnet.

Highlighting this line and pressing:

✓ enters the magnet settings menu

In the magnet settings menu, highlighting the MAGNET line and pressing:

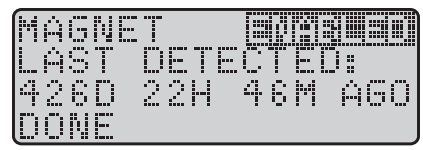
⊕ toggles magnet mode between ENABLED and DISABLED

⊖ toggles magnet mode between ENABLED and DISABLED

The neurostimulator contains a sensor that detects the presence of a strong magnet. It can be programmed to respond to a magnet in two different ways:

- **DISABLED.** The neurostimulator will ignore the presence of a magnet. If stimulation was on, it will stay on. If it was off, it will stay off.
- **ENABLED.** The neurostimulator will toggle stimulation output between on and off each time it detects a magnet. If stimulation was on it will turn off and vice versa.

The MAGNET SETTINGS screen also displays the elapsed time since a magnet was last detected. This information can help to identify magnet sources that are strong enough to be detected by the neurostimulator. The LAST DETECTED value will be displayed in days, hours, and minutes as shown in the following image.



NOTE: You can reset the “last detected” time by swiping the neurostimulator with a magnet.

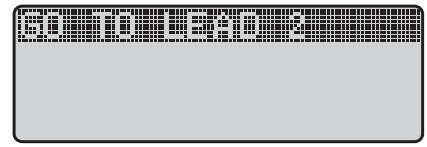
NOTE: The “last detected” feature works when the magnet is enabled and when it is disabled.

Switch Menu

GO TO LEAD 1 / GO TO LEAD 2

Use these options to move to (and program) the other lead on the Brio™ neurostimulator.

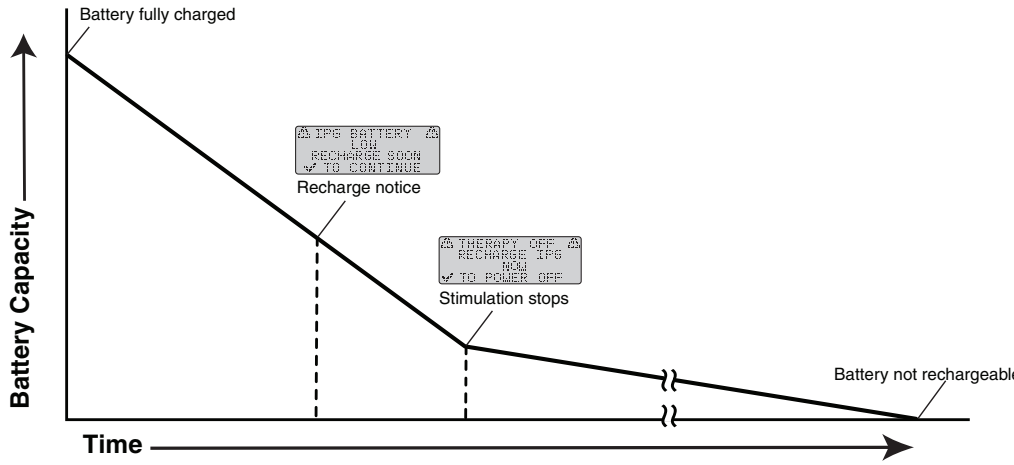
The following screen will be displayed to select lead 2 when programming lead 1. Lead 1 will be available for selection when programming lead 2.



MAINTAINING THE IPG BATTERY

The Brio™ IPG contains a lithium ion battery like a mobile phone. Therefore, recharging the battery more frequently can reduce charging session times and maximize the IPG's life. The patient, however, can use any recharge schedule that is convenient and that maintains effective therapy. The time it takes to recharge a battery depends on these factors: age of the battery, daily usage time, stimulation settings, and length of time since the last recharge.

The following graph depicts how the Brio rechargeable battery depletes over time.



If a patient does not recharge the IPG, the programmer eventually will display an IPG BATTERY LOW message. This reminder to recharge appears when the battery has less than half of its stimulation time remaining. If the patient does not recharge the battery, stimulation will eventually stop, and the patient then must recharge the battery to prevent battery damage. A newer battery can last up to 90 days before it must be recharged, while an older one must be recharged within 30 days.

WARNING: Do not let an IPG battery remain depleted for an extended period of time. If a depleted battery is not recharged within 30 to 90 days of its full discharge, the charger may not be able to recharge it; and it will have to be surgically replaced to resume therapy.

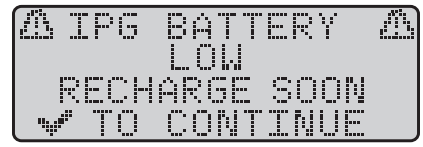
A rechargeable IPG will need replacement when stimulation can no longer be maintained with routine recharging. Battery usage studies demonstrate that, when used at high stimulation parameters, the Brio battery should allow at least ten years of practical recharging. At high stimulation parameters, a ten-year-old device will maintain at least 24 hours of continuous therapy between recharges. Depending on the patient's stimulation parameters, the device will continue to operate for months to years. If patients use lower stimulation parameters and/or a more frequent recharging protocol, they may experience a significantly longer device life before recharging is determined to be impractical.

The model used to predict device longevity was generated by fitting a mathematical model to three years of real-time cycling data, which was then used to extrapolate device battery capacity at the end of ten years.

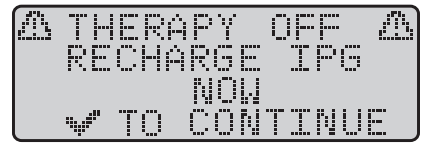
TROUBLESHOOTING

Neurostimulator Battery Warnings

Brio™ neurostimulators contain circuitry to detect when their battery voltage has fallen below a preset "low battery" level, and when it has fallen below a preset "therapy off" level designed as a battery safeguard. When this occurs, the programmer will display the corresponding warning.



IPG battery low warning



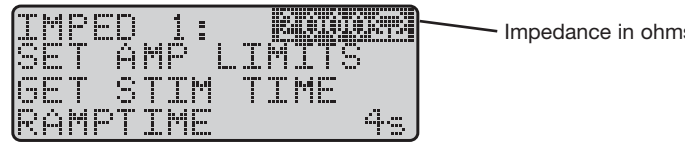
IPG therapy off screen

When the Therapy Off screen is displayed, the neurostimulator battery is very low, and the IPG needs to be recharged immediately. See the charging system manual for instructions on recharging the neurostimulator.

WARNING: If not recharged within 30 to 90 days after loss of stimulation, the IPG may lose its ability to be recharged, and will have to be surgically replaced.

Impedance Measurements

Impedance measurements can be helpful for troubleshooting problems. To obtain an impedance measurement, enter programming mode and use the CHECK IMPEDANCE action. After the impedance measurement is taken, the screen will appear as shown in the following image.

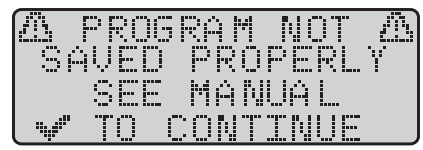


Keep in mind the following when interpreting impedance measurements:

- **RETRY.** The impedance value field will display RETRY when the impedance measurement timed out before obtaining an impedance value.
- **HIGH impedance readings.** The impedance will be reported as HIGH when the impedance measurement value is over 3000 ohms. This may indicate that there is an open circuit and that the selected electrodes may not be delivering the intended stimulation.
- **LOW impedance readings.** The impedance will be reported as LOW when the impedance measurement value is under 200 ohms. This may indicate that there is a short circuit and that the selected electrodes may not be delivering the intended stimulation.

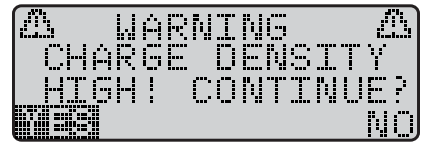
Program Not Saved Properly

The following message indicates that the stimulation program was not properly saved at the end of the prior programming session. The only option the programmer will offer is to enter programming mode so that the stimulation parameters can be reviewed and adjusted if necessary, and the program properly saved.



High Charge Density

The programmer automatically checks every amplitude and pulse width increase request to determine if it would cause the charge density to exceed 30 µC/cm^2. If so, it displays the charge density warning shown in the following image.



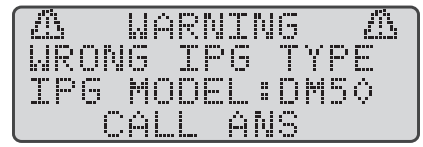
Selecting YES sends the requested increase to the neurostimulator and allows you to exceed the limit. While the charge density is being exceeded, a ⚠ warning symbol will appear on the AMP and PW lines, and on the Home screen. Selecting NO cancels the requested increase.

WARNING: A potential risk of tissue damage exists with high charge density stimulation. St. Jude Medical recommends that charge density not be exceeded.

Other Error and Warning Messages

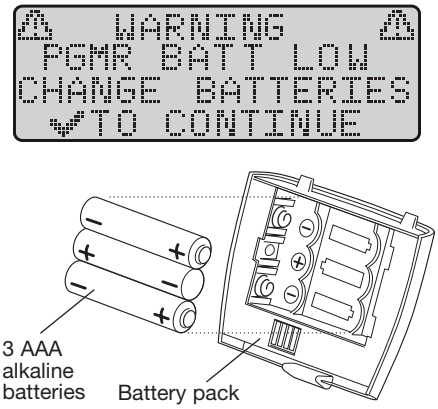
The following message appears if the programmer detects a problem with its circuitry or software. Try restarting the programmer and replacing the batteries. If that fails, call Customer Service to arrange service.

The following message appears if the programmer detects a neurostimulator that cannot be programmed with this model programmer. Call Customer Service for instructions.



The following message appears if the programmer detects an error in the neurostimulator or stimulation program. When this happens the neurostimulator is reset to its factory settings and turned off. Use the programmer to reprogram the neurostimulator and call Customer Service for assistance as required.

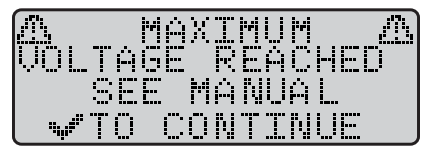
The following message appears when the programmer detects that its batteries are low. Remove the battery pack from the back of the programmer and replace the batteries with 3 new AAA batteries as shown.



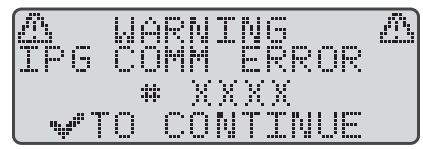
NOTE: Do not use rechargeable batteries. They may display an inaccurate battery capacity when you check your programmer's batteries.

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

The following message appears when the maximum electrical output is being delivered by the IPG. This may be caused by a high impedance, high stimulation amplitude, or open circuit. Check impedance to diagnose the issue.



The following error occurs when the programmer was unsuccessful in its attempt to communicate with the neurostimulator. It may be possible to correct this by repositioning the wand over the neurostimulator or moving away from sources of electromagnetic interference.



NOTE: If the COMM error occurs while you are in programming mode, you will be taken to the Home screen and required to re-enter programming mode.

NOTE: A COMM error may also occur if the IPG battery is depleted or the IPG is damaged. Recharge the IPG or contact Customer Service for assistance.

IPG Heating During Charging

During a charging session, it is normal if some patients perceive an increase in the temperature of the IPG. However, if the temperature of the IPG becomes uncomfortable for them, you should advise patients to try these troubleshooting tips:

- Stop charging until the discomfort subsides, and then resume charging.
- Use the charger belt and antenna holder that is provided with the charging system to hold the antenna in place.
- Reposition the charger antenna over the IPG site.
- Consider recharging more frequently for less time.
- Avoid tightly inserting the charger antenna between the body and a surface that may trap heat, such as a bed or chair.

CUSTOMER SERVICE INFORMATION

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

St. Jude Medical
6901 Preston Road
Plano, TX 75024
USA
+1 972 309 8000
+1 972 309 8150 Fax

EC REP

St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

WARRANTY

I. GENERAL WARNING

A. The St. Jude Medical™ Brio™ deep brain stimulation (DBS) system is comprised of implantable components, programmers, controllers, and patient accessories. The patient accessories may include a charging system and a magnet. The implantable components include leads, IPG, extensions, and accessories. Upon being implanted, these components must withstand exposure to an extremely hostile and unpredictable environment in the human body. The implanted components may fail during or following implantation into the body for any one or a number of reasons including, but not limited to, medical complications; body rejection phenomena; lead breakage; improper handling, implantation, or use; or insulation breach.

B. St. Jude Medical makes no representations or warranties that failure or cessation of function of any component, or the system, will not occur; that the body will not react adversely to implantation; or that medical complications will not develop.

II. LIMITED WARRANTY

A. LIMITATION OF WARRANTY

1. St. Jude Medical, 6901 Preston Road, Plano, TX 75024, USA, warrants the St. Jude Medical Brio DBS system to be free from defects in material or workmanship within one year from the date of implantation or ownership, subject to the terms and conditions contained in this warranty.

2. THIS WRITTEN LIMITED WARRANTY CONTAINS THE FINAL, COMPLETE, AND EXCLUSIVE STATEMENT OF WARRANTY TERMS FOR ST. JUDE MEDICAL BRIO DBS SYSTEMS, AND IT APPLIES IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED. ST. JUDE MEDICAL DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO PERSON IS AUTHORIZED TO MAKE ANY OTHER GUARANTEES, WARRANTIES, OR REPRESENTATIONS ON BEHALF OF ST. JUDE MEDICAL. This limitation may not apply to you because some states and countries prohibit the limitation or exclusion of implied warranties. You may have other rights under state law not specifically addressed in this limited warranty.

B. THIS LIMITED WARRANTY FOR THE BRIO DBS SYSTEM DOES NOT APPLY TO

1. Any damage caused by misuse, neglect, accident, modification, improper application, or from other than normal and ordinary use.
2. Any damage caused by any repair or attempted repair by anyone other than an authorized technician trained by St. Jude Medical.
3. Any damage resulting from failure to clean or use in accordance with the operating instructions and/or services manual furnished by St. Jude Medical.

C. LIMITATION OF DAMAGES

ST. JUDE MEDICAL DISCLAIMS LIABILITY FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGE ARISING OUT OF, OR IN CONNECTION WITH, THE USE OR PERFORMANCE OF THE SYSTEM, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT, WARRANTY, OR OTHERWISE. This limitation of liability applies to all warranty claims. No waiver or amendment of this limited warranty shall be valid unless in writing signed by St. Jude Medical. Some states, and countries, do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

III. IMPLANTABLE COMPONENTS

A. Subject to Sections I and II and paragraph III(B) of this limited warranty, if any of the implantable components should fail to function due to a defect in material or workmanship during the warranty period, St. Jude Medical will, at its option:

1. Replace the implantable component with an equivalent, or functionally equivalent, implantable component at no charge to the patient-consumer; or

2. Issue a credit to the patient-consumer for a replacement St. Jude Medical implantable component, the credit being equal to the net invoice price for the replaced implantable component.

B. For repair, replacement, or credit under this limited warranty

1. The implantable component must be implanted prior to the expiration date indicated on the component's packaging, and

2. If the implantable component is explanted, the patient-consumer, his or her authorized representative, physician or hospital, must return the component to St. Jude Medical. The patient-consumer, or his or her authorized representative, must, at his or her own expense, mail or ship the product together with a return number obtained from Customer Service to St. Jude Medical within 30 days after explantation. If the implantable component is not explanted, the component's serial number or lot number must be provided within 30 days after discovery of the defect.

3. Upon St. Jude Medical's receipt of the product, the returned implantable component shall become the exclusive property of St. Jude Medical.

IV. PROGRAMMERS, CONTROLLERS, AND PATIENT ACCESSORIES

A. Subject to Sections I and II and paragraph IV(B) of this limited warranty, if any Brio DBS system programmer, controller, or patient accessory fails to function due to a defect in material or workmanship during the warranty period, St. Jude Medical, at its option:

1. Repair any defective part of the programmer, controller, or accessory at no charge to the patient-consumer; or

2. Replace the programmer, controller, or accessory with an equivalent, or functionally equivalent, programmer, controller, or accessory at no charge to the patient-consumer; or

3. Issue a credit to the patient-consumer for a replacement St. Jude Medical programmer, controller, or accessory in an amount equal to the net invoice price for the defective programmer, controller, or accessory.

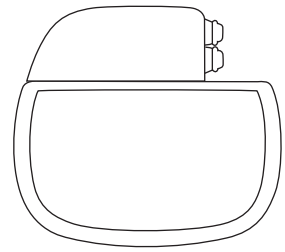
B. For repair, replacement, or credit under this limited warranty:

1. The patient-consumer, or his or her authorized representative, must, at his or her own expense, mail or ship the product together with a return number obtained from Customer Service to St. Jude Medical within 30 days after discovery of the defect.

2. Upon St. Jude Medical's receipt of the product, the returned component shall become the exclusive property of St. Jude Medical.

APPENDIX A: IPG SPECIFICATIONS AND KIT COMPONENTS

IPG Specifications



Model Number	6788
Height	4.8 cm (1.89 in)
Width	5.3 cm (2.1 in)
Thickness	0.95 to 1.1 cm (0.37 to 0.43 in)
Weight	29 g (1.0 oz)
Volume	17.7 cm^3 (1.08 in^3)
Power Source	Rechargeable lithium ion cell
Storage Temperature	-10°C to 55°C (14°F to 131°F)
Storage Humidity	10% to 90%
Storage Pressure	70 to 150 kPa (10.2 to 21.8 psi)
Connector Strength	Meets EN45502-1 requirements

Operational Specifications

Parameter	Range	Steps
Pulse Width	50 to 500 µs	12 µs/13 µs alternating
Frequency	2 to 240 Hz	10 Hz (increase)/2 Hz (decrease)
Amplitude	0 to 12.75 mA	0.05 to 0.75 mA

Kit Components

Each Model 6788 kit includes the following:

- 1 registration form
- 1 clinician's manual
- 1 identification card
- 1 torque wrench (Model 1101)
- 2 port plugs (Model 1111)
- 1 Brio™ IPG (Model 6788)
- 1 pocket sizer (included with Model 6788)

APPENDIX B: BRIO CLINICIAN PROGRAMMER SPECIFICATIONS AND KIT COMPONENTS

Programmer Specifications

Model Number	6851
Dimensions	6.8 x 10.77 x 2.6 cm (2.7 x 4.2 x 1 in)
Weight	128 g (4.6 oz)
Storage Temperature	-10°C to 55°C (14°F to 131°F)
Storage Humidity	10% to 90%
Storage Pressure	70 to 106 kPa (10.2 to 15.4 psi)
Operating Temperature	10°C to 40°C (50°F to 104°F)
Operating Humidity	30% to 75%
Operating Pressure	70 to 106 kPa (10.2 to 15.4 psi)
Classification	The clinician programmer is an internally powered device intended for continuous operation.

Kit Components

Each Model 6851 kit includes the following:

- 1 clinician's manual
- 3 AAA batteries
- 1 magnet (Model 1210)
- 1 communication wand (Model 1232)
- 1 battery pack (Model 1253)
- 1 carrying case (Model 1272)
- 1 Brio™ clinician programmer (Model 6851)

APPENDIX C: BRIO SYSTEM AND MRI SAFETY

Performing an MRI in patients implanted with this DBS system is contraindicated. MRI examinations of patients implanted with this DBS system should only be done if absolutely necessary and then only if these guidelines are followed. Consider all of the following risks before performing an MRI.

MRI ASTM Guidelines

Risks

The MRI environment has the potential to induce mechanical forces, such as deflection and torque, on the device. The potential also exists for heat generation at the location of the implanted electrodes due to MRI energy transferred through the implanted system. This isolated temperature rise may cause tissue damage at the location of the implanted electrodes, possibly resulting in severe injury or death. Additionally, implanted medical devices can interfere with the MRI to create artifacts in the resulting image. ASTM test standards have been developed to quantify these effects in order to evaluate the safety concerns involving MRI scans on patients with an implanted medical device.

Testing and Results from ASTM Guidelines

The testing described herein was performed using a 1.5-tesla Signa Excite MR system [GE Medical Systems, Milwaukee, WI, USA] with short-bore, actively shielded, horizontal static magnetic field. The gradient system parameters were: gradient ≤33 mT/m, slew rate ≤120 mT/m/ms, rise time ≥0.275 ms, dB/dt ≤46.2 T/s according to IEC 60601-2-33. The software release was 11.0_0403a. MR coil: transmit/receive head coil. dB/dt limit = 20 T/s.

For temperature measurements, the Brio™ DBS system was placed in a static, gelled saline human-shaped phantom consisting of 5.85 g polyacrylic acid and 0.8 g NaCl per liter of deionized distilled water. Temperatures were measured using a fiberoptic thermometer (FoTemp 4-N OPTOcon GmbH, Dresden, Germany).

Mechanical Forces

Testing was conducted on the Brio DBS system (also referred to as the Brio system) to determine the effect of the MRI environment on the implanted system. The MRI environment induced no mechanical forces on the leads or extensions used with the Brio system. This is explained by the lack of magnetic materials in these system components.

The Brio™ IPG experienced less MRI-induced deflection than the maximum deflection on the device due to gravity and less MRI-induced torque than the maximum torque on the device due to gravity. The ASTM standards consider the induced mechanical forces of torque and deflection from gravity to be a conservative criterion.

Induced Heating

Nonclinical testing was performed with a 1.5-tesla Signa Excite MR system with a Brio IPG and leads in clinically relevant position, bilateral and unilateral configuration, 4-channel and 8-channel leads, and laser

indicator head center. The Brio system with leads coiled at least 3 times near the burr hole (main lead coil plane perpendicular to B0; for more information on the effects of loops see the Baker reference) produced a maximum temperature rise of ≈6.5°C in a static human-shaped phantom with a background temperature increase of ≈0.4°C at a displayed head averaged (HA) specific absorption rate (SAR) of "3.1" W/kg (≈1 W/kg measured in a phantom calorimetric test) for 20 min. of MR scanning with transmit/receive head coil.

RF heating testing was only performed on a 1.5-T system. The Brio™ DBS system was only tested within a transmit/receive coil head coil.

The head averaged-SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the displayed WBA-SAR. Measurement inaccuracies and additional safety margins should be taken into account.

Previous studies of RF and other thermal ablation techniques have shown that reversible thermal lesions occur when the local temperature is elevated to the 42°C to 44°C range (a 5°C–7°C elevation over the normal body temperature of 37°C) and that irreversible thermal lesions occur when the local temperature is elevated above 45°C (8°C elevation over normal body temperature).

Use MRI parameters that limit the displayed local body SAR to ≤0.22 W/kg when using a transmit/receive head coil and a Brio system with leads coiled (≥1.5-cm diameter) at least 3 times near the burr hole (main lead coil plane perpendicular to B0). In addition, make sure that these lead coils are within the effective area of the transmit/receive head coil. This recommended local body SAR is based on a theoretical extrapolation to maintain localized temperature increases to ≤1°C based on in vitro test results, valid for test configuration only.

Gradient magnetic fields

Stimulation levels of ≈66% (1.5-tesla Signa Excite, GE Medical Systems) were used during RF heating testing from above. Note: dB/dt is not expressed in T/s, instead the distance from the stimulation threshold is given in percent. No tests have been performed on possible nerve or other tissue magnetic fields and resulting induced voltages.

Artifacts

Artifact testing was conducted on the Brio system to determine the extent of image distortion. Artifacts were reported to occur within 1.0 cm of the lead, 2.8 cm of the extension, 10.4 cm of the IPG. These artifact distances should be referenced to anticipate image distortion due to the implanted device. Implanted devices are unlikely to impair the diagnostic use of MRI when the area of interest is beyond the artifact distance listed for the specific device.

MRI Safety Guidelines

Implant Recommendations

- The Brio™ DBS system should be implanted as close to the centerline of the patient as possible, avoiding unnecessary offset of system components. Placement of system components further from the centerline will induce increased system heating at the exposed electrodes and may result in greater patient risk of severe injury or death
- Variations in device location and/or the location, number and size of loops of the lead or extension may cause increased system heating and tissue damage resulting in severe injury or death. Refer to the literature for more information on the effects of loops on MRI-related heating in DBS leads.
- Avoid implanting the IPG in the mid- to lower-torso of the patient and avoid unnecessary offset of the system.
- Avoid separation of the extensions when implanting the Brio system in a bilateral configuration. Unnecessary separation of the extensions may contribute to increased offset of the system along the y-axis of the magnet which may result in greater patient risk of severe injury or death.

Prescan Preparation

Before each MRI procedure, consider consulting medical experts and MRI physicists to discuss the situation with regard to the patient benefit.

- An appropriate healthcare professional with access to a programmer that is compatible with the Brio DBS system should be available to assist and prepare the patient for the MRI procedure as follows. If the IPG has already been implanted, record the patient's current therapeutic settings, then set the IPG's amplitude to 0 mA; set the IPG magnet mode to "Disabled"; and turn the IPG output off.
- Use an approved diagnostic imaging technique to review the patient's implant configuration, including system offset from patient centerline and loop quantity, size, and placement.
- The patient should be in a position such that the implanted system is positioned along the centerline of the magnet.
- Instruct the patient to alert the MRI system operator of any problems, such as heating, shocks, vision impairment, or any sensation or discomfort, so the operator can terminate the MRI if necessary.

NOTE: Energy from MRI transferred through the implantable system occurs very rapidly. In cases that excess heat generation does occur, the onset may be immediate and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

CAUTION: Due to the risk of localized heating that may result in tissue damage, MRI procedures should not be performed on patients with any DBS system that is suspected to have a broken lead or extension wire. If a broken lead or extension wire is suspected, an X ray should be obtained prior to an MRI to verify the presence of the broken wire. Additionally, a Brio-compatible programmer may be used to test for an open circuit due to broken lead or extension wires.

MRI Scanner Parameters and Settings

MRI safety testing was conducted on a static, gelled saline human-shaped phantom using a 1.5-tesla Signa Excite MR system [GE Medical Systems] with short-bore, actively shielded, horizontal static magnetic field. The gradient system parameters were: gradient ≤33 mT/m, slew rate ≤120 mT/m/ms, rise time ≥0.275 ms, dB/dt ≤46.2 T/s according to IEC 60601-2-33. The software release was 11.0_0403a. MR coil: transmit/receive head coil. dB/dt limit = 20 T/s. All testing data and guidelines are limited to this system.

Use MRI parameters that limit the displayed local body SAR to ≤0.22 W/kg when using a transmit/receive head coil and a Brio system with leads coiled (≥1.5-cm diameter) at least 3 times near the burr hole (main lead coil plane perpendicular to B0). In addition, make sure that these lead coils are within the effective area of the transmit/receive head coil.

CAUTION: Due to the lack of supporting evidence otherwise, it must be assumed that the automatic calculations determining SAR may be different for each MR scanner, inclusive to brands and models. The inherent variations in SAR calculations per scanner must be taken into consideration with respect to the data and recommendations reported in this guidance document. Increased system heating from inconsistent SAR calculations may cause tissue damage resulting in severe injury or death. Therefore, MRI scans should be treated as conservatively as possible since calculated SAR values cannot be assumed equivalent for all scanners.

The guidelines provided are limited to the Brio™ DBS system. Do not use a whole-body RF coil, a head coil that extends over the chest area, a head coil that is not both a transmit and receive type RF coil, or other extremity coils.

APPENDIX D: ELECTROMAGNETIC COMPATIBILITY GUIDELINES

The Brio™ clinician programmer (Model 6851), hereafter the device, is medical equipment and should be used with the following guidance:

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device was tested for basic safety and essential performance, as defined by IEC 60601-1/AMD1:2012 (Edition 3.1). Performance of the device was maintained during electromagnetic disturbance testing.

The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

CAUTION: The device complies with the limits for medical devices contained in IEC 60601-1-2:2014-04 and CISPR11:2015 (BS EN 55011:2016).
However, the device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device.

CAUTION: To avoid increasing emissions or decreasing immunity from a device or system, use only components approved by St. Jude Medical with this system. Do not use St. Jude Medical™ components with devices or systems that are not approved by St. Jude Medical.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device produces RF emissions due to its internal and system interface functions. 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 87.5 kHz. The field strength is 32 dBµA/m at 3 m (inductive couple device).

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 5%.
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 line ±2 kV line to ground	Not applicable	No guidance for battery-powered devices.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
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	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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms (ISM/Radio bands between 150 kHz to 80 MHz) 80% AM at 1 kHz	6 Vrms	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. Recommended minimum separation distance for higher immunity test levels $E = \frac{6}{d}\sqrt{P}$ where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	

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

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

Guidance and Manufacturer's Declaration – Proximity Fields			
Proximity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance d = 0.3 m
	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	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	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	

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the device, including cables specified by St. Jude Medical. Otherwise, performance degradation may occur.

APPENDIX E: CE MARK DATE

The following table lists the year in which the CE mark was awarded by model number.

Model	Year
1101	1999
1210, 1232, 1253, 1272	2000
1111	2008
6788, 6851	2009

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