St. Jude Medical™ Patient Controller

For Deep Brain Stimulation Systems
Model 3875

USER'S GUIDE

ST. JUDE MEDICAL

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

Contents

About This Guide

This guide explains how to use the St. Jude Medical™ Patient Controller application (Model 3875) with your neurostimulation system. If you have any questions about your system, contact Technical Support.

Symbols and Definitions

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

> NOTE: For symbols and definitions for the patient controller, refer to the Apple™ manual available at http://www.apple.com/support/ipodtouch/; or on the patient controller Home screen, tap **Settings** > **General** > **About** > **Legal** > **Regulatory**. (Apple™ is a trademark of Apple Inc.)

Table 1. Symbols and definitions

Symbol	Definition
	Caution, consult accompanying documents
	Consult this document for important safety-related information (This symbol is blue and white on the device.)

Table 1. Symbols and definitions

Symbol	Definition
	Consult instructions for use
	Device contains a type BF applied part to protect you from shock. The device is internally powered and is intended for continuous operation.
	Device contains a radio-frequency (RF) transmitter, which may cause RF interference with other devices near this device.
	Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Expiration date
	Date of manufacture
	Catalog number
	Manufacturing facility
	Manufacturer

Table 1. Symbols and definitions

Symbol	Definition
	Do not use if the product sterilization barrier or its packaging is compromised
	Contents quantity
	Batch code
	Prescription use only

Table 1. Symbols and definitions

Symbol	Definition
	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.
EC REP	Authorized European representative
Australian Sponsor	Australian Sponsor

Table 1. Symbols and definitions

Symbol	Definition
CE 0086	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

Terms Used in This Document

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

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

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

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The St. Jude Medical™ neurostimulation system is designed to deliver electrical stimulation to targets in the brain. The St. Jude Medical™ Patient Controller app is intended to be used as part of the system to help the patient manage prescribed stimulation programs.

Indications for Use

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

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

Contraindications

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

- Are unable to operate the system
- Have unsuccessful test stimulation

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

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

Warnings

The following warnings apply to this neurostimulation system.

> NOTE: For non-therapy related warnings regarding the St. Jude Medical™ Patient Controller, refer to the Apple™ manual available at http://www.apple.com/support/ipodtouch/.

System Warnings

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

Magnetic resonance imaging (MRI). Do not perform an MRI on a patient with any implanted neurostimulator or lead (or any portion of a lead). Even if the neurostimulator has been removed, the patient should not have an MRI if any part of a lead or the cranial prosthesis is still implanted. The neurostimulation system is MR unsafe. Testing has not been performed to define conditions of use to ensure safety of the neurostimulation system in an MR environment.

High stimulation outputs and charge density limits. Avoid excessive stimulation. A risk of brain tissue damage exists with parameter settings using high amplitudes and wide pulse widths. High amplitudes and wide pulse widths should only be programmed with due consideration of the warnings concerning charge densities. The system can be programmed to use parameter settings outside the range of those used in the clinical studies. If the programming of stimulation parameters exceeds the charge density limit of 30 $\mu C/cm^2$, a screen will appear warning you that the charge density is too high. Charge density can be reduced by lowering the stimulation amplitude or pulse width. For more information, see the clinician programmer manual.

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

Risk of depression, suicidal ideations, and suicide. Depression, suicidal ideation, and suicide have been reported in patients receiving deep brain stimulation therapy for movement disorders, although no direct cause and effect relationship have been established. Note the presence of any of the following symptoms and discuss them with your clinician: depression,

suicidal thoughts, or behaviors, changes in mood, and impulse control. Sustained follow-up and support with your clinician, caregivers and family members is very important.

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

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

Electrosurgery devices. Electrosurgery devices may harm you or damage your neurostimulation system. If you need to receive a procedure using an electrosurgery device, place your generator in Surgery Mode. Your physician may only use bipolar electrosurgery devices and they should keep the device as far away from your neurostimulation system as possible. Additionally, they must confirm the neurostimulation system is functioning correctly after your procedure.

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

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

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

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

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

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

Return of symptoms and rebound effect. The abrupt cessation of stimulation for any reason will probably cause disease symptoms to return. In some cases, symptoms may return with a greater intensity than what a patient experienced before system implantation (rebound effect). In rare cases, this can create a medical emergency.

Emergency procedures. Designate a representative (family member or close friend) to notify any emergency medical personnel of your implanted neurostimulation system if emergency care is required. You will receive an identification card to carry that will inform emergency medical personnel of your implanted system. Use caution when undergoing any procedure that could include radiofrequency (RF) or microwave ablation, defibrillation, or cardioversion.

Device Warnings

Explosive or flammable gases. Do not use the device in an environment where explosive or flammable gas fumes or vapors are present. Operating the device could cause it to ignite, causing severe burns, injury, or death.

Interference with other devices. This equipment can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other active implanted devices. Avoid placing equipment components directly over other electronic devices. To correct the effect of interference with other devices, turn off the equipment or increase the distance between the equipment and the device being affected.

Application modification. To prevent unintended stimulation, do not modify the operating system in any way. Do not use the application if the operating system is compromised (i.e., jailbroken).

Strangulation. The cords in this system pose a strangulation risk. To avoid strangulation, be careful when using cords and keep cords out of the reach of children.

Precautions

The following precautions apply to this neurostimulation system.

> NOTE: For nontherapy related precautions for the St. Jude Medical™ Patient Controller, refer to the Apple™ manual available at http://www.apple.com/support/ipodtouch/.

General Precautions

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

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

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport

security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Use caution when approaching such a device and request help to bypass the device. If you must go through or near a gate or doorway containing this type of device, move quickly and then check your IPG to determine if it is turned on or off.

Unauthorized changes to stimulation parameters. Do not make unauthorized changes to physician-established stimulation parameters.

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

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

Handling and Implantation

Component manipulation. Do not rub or press on implanted components through the skin. This may cause the leads to move leading to stimulation at the implant site, IPG inversion leading to the inability to communicate with the device, or skin erosion that can lead to another surgical procedure or possible infection.

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

Hospital and Medical Environments

Medical tests and procedures. Before undergoing medical tests or procedures (such as therapeutic radiation or electrolysis), contact your physician to determine if the procedure will cause you injury or damage your neurostimulation system. Specifically, you should be aware that medical devices such as electrohydraulic lithotriptors, therapeutic X rays, computerized tomography (CT) scans, cobalt machines, and linear accelerators may cause damage to the electronic circuitry of an implanted neurostimulation system.

Electrical medical treatment. In the case that a medical treatment is administered where an electrical current is passed through the body from an external source, first deactivate the IPG by setting all electrodes to off, turning stimulation off, and setting

the stimulation strength to zero. Regardless if the device is deactivated, take care to monitor the device for proper function during and after treatment.

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

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

External defibrillators. Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established. External defibrillation can cause induced currents in the lead-extension portion of the neurostimulation system. After defibrillation, confirm the neurostimulation system is still working.

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

Electrocardiograms. Ensure the neurostimulator is off before initiating an electrocardiogram (ECG). If the neurostimulator is on during an ECG, the ECG recording may be adversely affected, resulting in inaccurate ECG results. Inaccurate ECG results may lead to inappropriate treatment of the patient.

Home and Occupational Environments

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

Activities requiring excessive twisting or stretching. Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive bending, twisting, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the

component.

Component manipulation by patient. Patients should avoid manipulating the implanted system components (e.g., the neurostimulator, the burr hole site). This can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. Manipulation may cause device inversion, inhibiting the ability to use the magnet to start or stop stimulation.

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

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

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

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

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

Physician instructions. Always follow the programs and therapy instructions established for you by your physician. If you do not, the therapy may be less effective.

Patient training. Do not use your neurostimulation system until an authorized clinician has trained you how to control stimulation and safely use the system.

Magnet usage. The magnet provided with the system is a high-powered magnet intended for use solely with the system. Keep it away from watches, credit cards, computer disks, and other magnetically sensitive items to avoid damaging them. Always place the keeper bar on the magnet when not in use.

Home use. This product is intended for home use per physician instruction. To avoid damage and other potential hazards, keep this product away from children and pets.

Wireless use restrictions. In some environments, the use of wireless functions (e.g., Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, in hospitals, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on. (Bluetooth® is a registered trademark of Bluetooth SIG, Inc.)

Device Precautions

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

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

Control of your device. Keep your device out of the hands of children in order to avoid potential damage or unauthorized change in stimulation parameters.

Battery precaution. This device contains a lithium ion battery as well as other potentially hazardous materials. Do not crush, puncture, or burn the device because explosion or fire may result. Return it to St. Jude Medical for proper disposal.

Device modification. This 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.

Adverse Effects

Deep brain stimulation potentially has the following adverse effects:

Possible surgical complications. Surgical complications include, but are not limited to, the following: intracranial hemorrhage (which can lead to stroke, paralysis, or death); subcutaneous hemorrhage or seroma; hematoma; cerebrospinal fluid leakage or cerebrospinal fluid abnormality; brain contusion; infection or inflammation; antibiotic anaphylaxis; skin disorder; edema; persistent pain at surgery site or IPG site; erosion; brachial plexus injury (nerves to chest, shoulder and arm); postoperative pain, stress, or discomfort; neuropathy (nerve degeneration); hemiparesis (muscular weakness or

partial paralysis on one side of body); ballism or hemiballism (uncontrollable movements on both or only one side of the body); confusion—transient, nocturnal or ongoing; cognitive impairment, including delirium, dementia, disorientation, psychosis and speech difficulties; aphasia; deep vein thrombosis; complications from anesthesia; phlebitis (vein inflammation); pulmonary embolism (sudden blood vessel obstruction); aborted procedures (air embolism, unable to find target, surgical complication, etc.); complications from unusual physiological variations in patients, including foreign body rejection phenomena; pneumonia, seizure or convulsions; paralysis (loss of motor function, inability to move); stroke and death.

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

- Device-related complications
  - Undesirable changes in stimulation related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections, or lead fracture
  - Loss of therapeutic benefit as a result of change in electrode positions, loose electrical connections, or lead or extension fracture
  - Initial jolt or tingling during stimulation; jolting or shocking sensations
  - Infection

- Paresthesia
- Lead fracture, migration, or dislodgement
- Misplaced lead
- Extension malfunction, fracture, or disconnect
- Deep brain stimulation system failure or battery failure within the device
- Deep brain stimulation system malfunction or dislodgement
- Spontaneous turning on or off of the IPG
- Allergic or rejection response to implanted materials
- Persistent pain, tightness, or redness at the incision sites or general pain
- General erosion or local skin erosion over the IPG
- Persistent pain, tightness, or discomfort around the implanted parts (e.g., along the extension path in the neck)
- Impaired wound healing (e.g., incision site drainage) or abscess formation
- Additional neurosurgical procedure to manage one of the above complications or to replace a malfunctioning component

▪ Stimulation-related complications or other complications
  - Worsening of motor impairment and Parkinson's disease symptoms including

dyskinesia, rigidity, akinesia or bradykinesia, myoclonus, motor fluctuations, abnormal gait or incoordination, ataxia, tremor, and dysphasia

- Paresis, asthenia, hemiplegia, or hemiparesis
- Dystonia
- Sensory disturbance or impairment including neuropathy, neuralgia, sensory deficit, headache, and hearing and visual disturbance
- Speech or language impairment including, aphasia, dysphagia, dysarthria, and hypophonia
- Cognitive impairment including attention deficit, confusion, disorientation, abnormal thinking, hallucinations, amnesia, delusions, dementia, inability to act or make decisions, psychic akinesia, long term memory impairment, psychiatric disturbances, depression, irritability or fatigue, mania or hypomania, psychosis, aggression, emotional lability, sleep disturbance, anxiety, apathy, drowsiness, alteration of mentation, postural instability and disequilibrium
- Restless leg syndrome
- Supranuclear gaze palsy
- Hypersexuality or increased libido

- Decreased therapeutic response
- Urinary incontinence or retention
- Diarrhea or constipation
- Cardiac dysfunction (e.g., hypotension, heart rate changes, or syncope)
- Difficulty breathing
- Increased salivation
- Weight gain or loss
- Eye disorder including eye apraxia or blepharospasm
- Nausea or vomiting
- Sweating
- Fever
- Hiccups
- Cough
- Cramps
- Worsening existing medical conditions

Patient Expectations

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

As with any surgery or therapy, deep brain stimulation has risks and complications. See the "Adverse Effects" (page 22) for a list of complications associated with deep brain stimulation. Most side effects of deep brain stimulation surgery are temporary and are resolved within the first few months. However, some complications can be more serious or permanent. In the event that side effects are intolerable or you are not satisfied with the therapy, the deep brain stimulation system can be turned off or usually it can be surgically removed. You also need to be aware that you cannot undergo diathermy procedures, electroshock therapy, transcranial magnetic stimulation or MRIs as discussed in "Contraindications" (page 7). Talk to your doctor about the risks associated with placement and use of a deep brain stimulation system.

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

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

Product Description

The St. Jude Medical™ Patient Controller application (Model 3875) allows you to view, select, and control the programs that your physician has prescribed. The St. Jude Medical™ Patient Controller communicates wirelessly with the generator.

NOTE: Do not install additional applications on the St. Jude Medical™ Patient Controller. Contact St. Jude Medical before upgrading the iOS™ software on your device. After upgrading, make sure you download the latest St. Jude Medical™ Patient Controller app from the Public App store. (iOS™ is a trademark of Cisco Technology, Inc.)

NOTE: In this document, the term "patient controller" refers to the St. Jude Medical™ Patient Controller device and "patient controller app" refers to the St. Jude Medical™ Patient Controller application (app).

About Your System

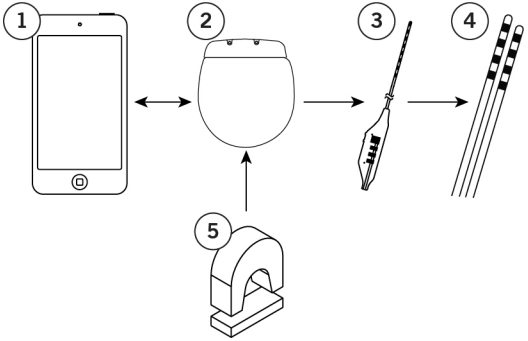
This neurostimulation system is designed to deliver electrical stimulation to targets in the brain. The neurostimulation system includes the following primary components:

- Implantable pulse generator (IPG)
- Extensions
- Leads
- Patient controller
- Patient magnet

The IPG connects to the implanted extensions, which connect to the leads implanted in the brain. The IPG delivers electrical pulses through the extensions and leads to electrodes at a selected target in the brain in order to provide therapeutic stimulation. The patient magnet can turn the IPG on and off if the physician enabled this functionality. Physicians use the clinician programmer to create and modify a program for a patient. Patients use the patient controller to control their prescribed program.

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

Figure 1. Interaction between major system components



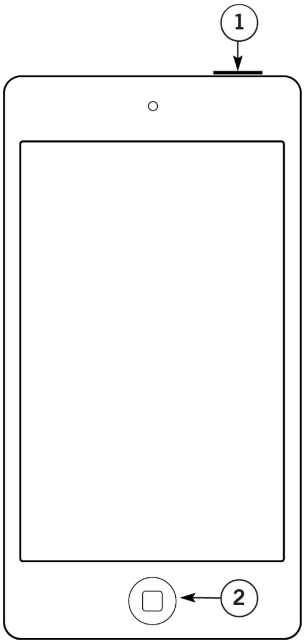
1. Patient controller
2. IPG
3. Extensions
4. Leads
5. Patient magnet

Overview of the Patient Controller

Refer to the following figure for the patient controller features.

NOTE: For nontherapy related information on how to use the patient controller, refer to the Apple™ manual available at http://www.apple.com/support/ipodtouch/.

Figure 2. Patient controller features



1. Power button
2. Patient controller Home button

Table 2. Patient controller feature descriptions

Power button	To turn the patient controller on, press and hold the Power button until the Apple™ icon appears. To turn the patient controller off, press and hold the Power button until the *slide to power off* bar appears, and then slide the bar to the right. To wake the patient controller from sleep mode, press the Power button. To unlock the patient controller, slide the *slide to unlock* bar to the right. To place the patient controller in sleep mode, press the Power button.
Patient controller Home button	Press the patient controller Home button to return to the patient controller Home screen. To wake the patient controller from sleep mode, press the patient controller Home button.

Table 2. Patient controller feature descriptions

Touch screen swipe functionality	To swipe the screen to the right, touch the left side of the screen and briefly drag your finger to the right side, and then lift your finger from the screen. Use the same general steps to swipe the screen left, up, or down.

Items You Will Receive

In addition to the product documentation, you will receive the following items to use with your system:

- Patient controller and charging cord
- Protective case for the patient controller
- Magnet

Your Personal Identification Card

A personal medical identification card is included with your product documentation. This card does the following things:

- Identifies you as having an implanted medical device
- Helps you pass through security systems like those in airports

- Provides information that allows your physician to be contacted in an emergency

If you have questions about your card, contact Technical Support.

Directions for Use

Read this section for instructions on how to use the patient controller app. If you do not have the app downloaded, see "Appendix A: Downloading the Patient Controller App" (page 68) for instructions.

Start-up Screen

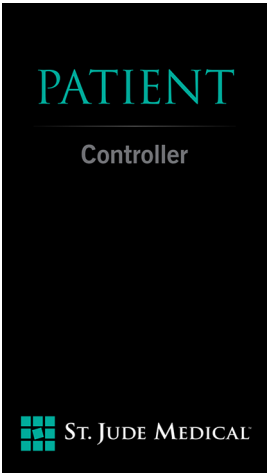
Tap the patient controller app icon on the patient controller Home screen to launch the app. The patient controller app automatically connects to your generator. If you have multiple generators, you will need to select the generator from the list.

> NOTE: If you need to pair your patient controller and generator, see "Appendix B: Pairing the Patient Controller to the Generator" (page 70) for instructions.

While your app starts up, you will see the following Start-up screen.

> NOTE: The patient controller app times out after 3 minutes of inactivity.

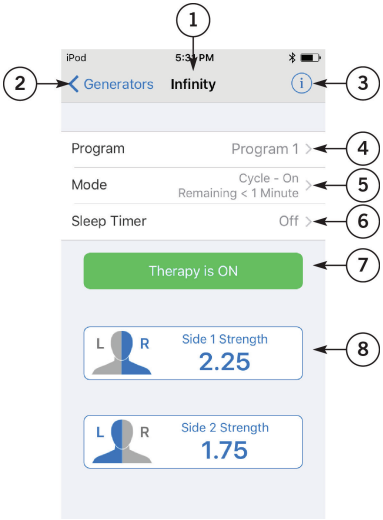
Figure 3. Start-up screen



Overview of the Therapy Screen

After the patient controller app connects with the generator, the Therapy screen appears.

Figure 4. Therapy screen



1. Screen title
2. Generators button
3. Information icon
4. Program name
5. Mode
6. Sleep Timer
7. Therapy button
8. Strength button

Table 3. Therapy screen descriptions

Screen Section or Button Name	Description
Screen title	Displays the name of the screen you are viewing.
Generators button	Tap the Generators button to display the Generator List screen and end the session with the current generator.
Information icon	Tap the Information icon to display the System screen. See "System Information" (page 52) for more information.
Program name	Displays the name of the active program. Tap to display the Programs screen. See "Viewing and Selecting a Program" (page 47) for more information.

Table 3. Therapy screen descriptions

Screen Section or Button Name	Description
Mode	Displays the active program mode (Continuous or Cycle). Tap to display the Mode screen and enable Airplane Ready mode or Surgery Mode. See "Program Mode" (page 42) for more information.
Sleep Timer	Displays the amount of time until therapy turns off. Tap to display the Sleep Timer screen. See "Program Mode" (page 42) for more information.
Therapy button	Displays whether therapy is on or off. Tap to turn therapy on or off. See "Adjusting Program Strength" for more information.

Table 3. Therapy screen descriptions

Screen Section or Button Name	Description
Strength button	Displays the active program stimulation strength level. Tap to display the Strength screen. You will not see this button if your physician has not programmed you to modify your program strength. See "Adjusting Program Strength" for more information.

Starting and Stopping Stimulation

You may start and stop stimulation using the patient controller app or the included magnet if your physician enabled magnet use.

To start or stop stimulation using the patient controller app, perform one of the following:

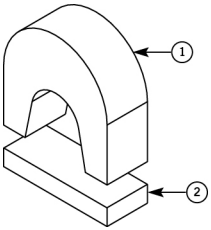
- Tap the Therapy is ON or Therapy is OFF button on the Therapy screen to turn stimulation on and off.

  NOTE: When you turn stimulation on from the Therapy screen, stimulation strength will gradually return to the target strength.

To start or stop stimulation using the magnet, follow these steps:

1. Take the keeper bar off the magnet.

Figure 5. Magnet and keeper bar



1. Magnet
2. Keeper bar

2. Hold the magnet perpendicular to and centered directly over the generator site.
3. Hold the magnet in place for 2 seconds.
4. Remove the magnet, replace the keeper bar, and store the magnet.

   Stimulation will either start (using the most recently used program) or stop.

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

Program Mode

Depending on the programmed mode, Continuous or Cycle is displayed on the Therapy screen.

- Continuous – provides nonstop stimulation
- Cycle – automatically alternates between on and off for the preset stimulation periods in the selected Program; displays the remaining time in the current Cycle – On or Cycle – Off mode

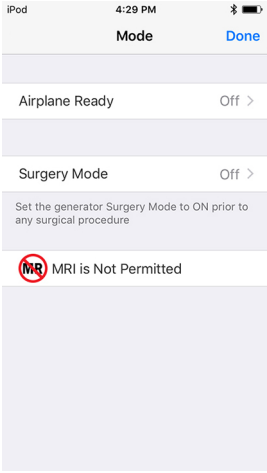
The Sleep Timer displays the remaining stimulation time or Off if the Sleep Timer is off.

- Tap **Sleep Timer** on the Therapy screen to open the Sleep Timer screen, then tap the desired amount of time until stimulation turns off.

Tap **Mode** to open the Mode screen. From this screen you may place your system in Airplane Ready mode or enable Surgery Mode.

- To enable Airplane Ready mode, tap **Airplane Ready** to view the Airplane Ready screen. Follow the instructions on the screen to turn Airplane Ready on or off. For instructions about turning Bluetooth® wireless technology on, see "Troubleshooting" (page 56).
- For more information about Surgery Mode, see "Using the Surgery Mode Feature" (page 43).

Figure 6. Mode screen



Using the Surgery Mode Feature

This section provides information and instructions about what you need to do before and after a surgical procedure. Using this feature turns therapy off while you undergo your procedure.

> NOTE: If you feel uncomfortable completing the following steps, contact St. Jude Medical before your procedure. Contact your clinician before your procedure to learn more about any risks.

Preparing for a Surgical Procedure

If you are going to undergo a surgical procedure, follow these guidelines:

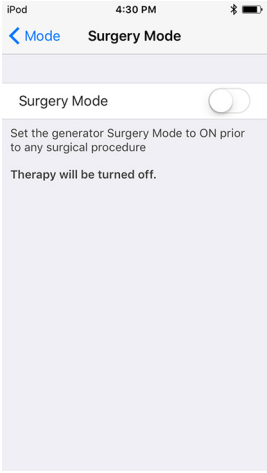
- Set your IPG to Surgery Mode before your procedure. See "Setting the IPG to Surgery Mode" (page 44) for instructions.
- Charge your patient controller before the procedure.
- Bring your identification card and patient controller to the procedure.

Setting the IPG to Surgery Mode

To set your IPG into Surgery Mode, follow these steps:

1. From the Therapy screen, tap **Mode** to display the Mode screen.
2. Tap **Surgery Mode** to view the Surgery Mode screen.

Figure 7. Surgery Mode screen



3. Tap the **Surgery Mode** toggle button.

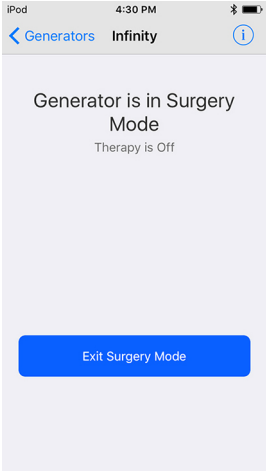
   Stimulation stops and you may undergo your surgical procedure.

Disabling the Surgery Mode

After your procedure, you need to disable Surgery Mode to restart stimulation. To disable Surgery Mode, follow these steps:

1. Launch the patient controller app and connect with your generator. You should see the following screen, showing that the IPG is in Surgery Mode.

Figure 8. Generator is in Surgery Mode screen



2. Tap **Exit Surgery Mode**. The patient controller app disables Surgery mode. The Therapy screen appears, showing that stimulation therapy is off.
3. To start stimulation, tap **Therapy is OFF**.

Viewing and Selecting a Program

Tap the program name on the Therapy screen to open the Programs screen. On the Programs screen you can view and select any of the saved programs.

To navigate between the saved programs, either:

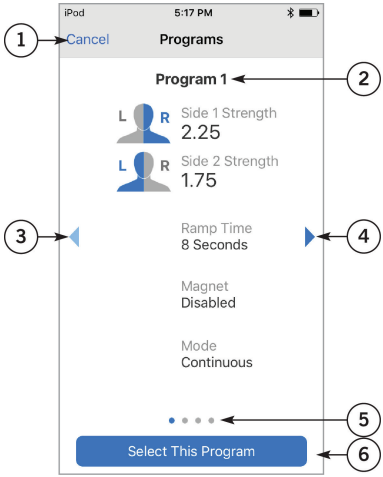
- Swipe the screen right or left in the area containing the program information
- Tap the right or left arrows

To select a program:

- When you locate the program you want to activate, tap **Select This Program**.

  NOTE: When you select a new program, stimulation strength will gradually increase to the target strength set for the selected program.

Figure 9. Programs screen



1. Cancel button
2. Program name
3. Left arrow
4. Right arrow
5. Program indicator
6. Select This Program button

Table 4. Programs screen descriptions

Screen Section or Button Name	Description
Cancel button	Tap **Cancel** to return to the Therapy screen. No program changes will be made.
Program name	Displays the program name of the current Programs screen. A check mark next to the program name indicates the currently selected program.
Left and right arrows	Tap the left and right arrows to scroll through your saved programs.
Program indicator	Displays the number of programs available and indicates which program is on the screen.
Select This Program button	Tap **Select This Program** to select the currently displayed program as your active program.

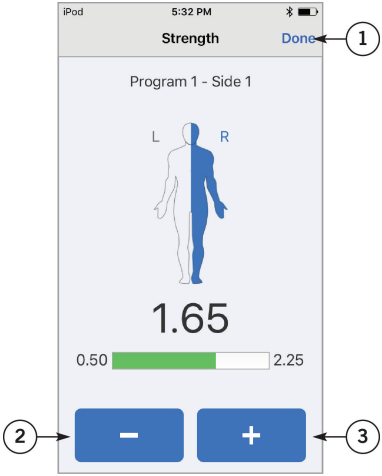
Adjusting Strength

Tap **Strength** on the Therapy screen to open the Strength screen. On the Strength screen you can modify strength for the selected side.

- Tap the + or – buttons to increase or decrease strength.

  The number and green bar above the buttons will increase or decrease as you increase or decrease strength.

Figure 10. Strength screen



1. Done button
2. Decrease button
3. Increase button

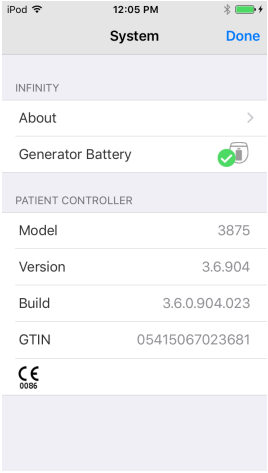
Table 5. Strength screen descriptions

Screen Section or Button Name	Description
Done button	Tap **Done** to save changes and return to the Therapy screen.
Increase button	Tap to increase the strength for the selected side.
Decrease button	Tap to decrease the strength for the selected side.

System Information

Tap ⓘ on the Therapy screen to display the System screen. This screen displays the information for your patient controller app and generator, such as the generator battery status, the patient controller app model number, and the software version. You can also view information about your generator, such as the model number.

Figure 11. System screen



Maintaining the Generator and Patient Controller

This section provides tips and other information about maintaining your generator and patient controller.

Checking the Generator Battery Status

As the battery is used, the generator battery indicator on the System screen shows the battery status. When the battery status is good,  is displayed; and when the battery is approaching the end of service,  is displayed. How long the battery lasts depends on the programmed stimulation settings, how often stimulation is used, and how often you communicate with the generator, so communicate with your generator only when necessary.

NOTE: When the generator battery is approaching the end of service a warning pops up on your patient controller app.

NOTE: You may also receive low battery warnings regarding the patient controller, so make sure to read the warning before dismissing.

Checking the Patient Controller Battery Status

You can view the patient controller battery status in the top right corner of the screen, see "Start-up Screen" (page 35). As the battery is used, the battery indicator shows the remaining charge. Recharge the patient controller using only the provided Apple™ charging cord and wall outlet plug.

> NOTE: Keep the patient controller charged or have a power supply nearby. Familiarize yourself with the patient controller's battery life so you can anticipate its recharging needs. For further information, refer to the Apple™ manual available at http://www.apple.com/support/ipodtouch/.

Caring for the Patient Controller

Clean the protective case for the patient controller by wiping off the outer surface using a moist cloth and a small amount of mild soap. Do not use a cloth that is saturated. Do not use alcohol, ammonia-based cleaning agents, cleaning solutions, or solvents to clean the case.

> NOTE: For further information on how to care for the patient controller, refer to the Apple™ manual available at http://www.apple.com/support/ipodtouch/.

Protecting Access to the Patient Controller

To prevent unauthorized access to your patient controller app, set up a passcode using the instructions provided in the Apple™ manual at http://www.apple.com/support/ipodtouch/.

Troubleshooting

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

> NOTE: If you encounter problems other than those described in this section or if your device is lost or damaged, contact Technical Support.

Table 6. Troubleshooting messages

Message	Solution
Turn On Bluetooth to Access Generator	Turn on Bluetooth® wireless technology on your patient controller if communication is disabled. 1. Press the patient controller Home button.

Table 6. Troubleshooting messages

Message	Solution
	2. Tap Settings on the patient controller Home screen. 3. Tap Bluetooth, and then tap the Bluetooth wireless technology toggle button. NOTE: If you turn Bluetooth wireless technology off and on or reset the app then it will take longer to reconnect to your generator.
System Problem The system encountered a problem. Contact SJM if this problem persists.	Try the action again. If you continue to encounter this problem, contact Technical Support.

Table 6. Troubleshooting messages

Message	Solution
Generator Unavailable Make sure the generator is in range and has enough battery power.	Make sure your generator is in range and the battery has enough charge (see "Checking the Generator Battery Status" (page 54)), then try connecting to your generator again. If your generator does not have enough battery power, contact your physician.
Generator Not Connected Connect to the generator to adjust your therapy.	Your connection has timed out. Reconnect to your generator.
Connection Problem with the Generator	Try connecting to your generator again. If you continue to encounter this problem, contact Technical Support.

Table 6. Troubleshooting messages

Message	Solution
Connection Lost A magnet was used to place the generator in the Bluetooth pairing mode.	Try connecting to your generator again. If you continue to encounter this problem, contact Technical Support.
Connection Not Ready This device was not ready to find the generator.	Try connecting to your generator again. If you continue to encounter this problem, contact Technical Support.
Replace Generator Soon The generator is approaching its end of service and will need to be replaced soon. Contact your physician to schedule a replacement.	Contact your physician.

Table 6. Troubleshooting messages

Message	Solution
Replace Generator The generator has reached the end of its service. Contact your physician to schedule a replacement.	Contact your physician.
Therapy is OFF Therapy was turned off because the program needed to be reset.	Tap **Dismiss**.
Therapy is OFF You will need to select another program.	Tap **View Programs** to select another program.
Strength was Decreased The generator could not deliver the desired strength. Contact your clinician if the problem persists.	Try adjusting strength again. If you continue to encounter this problem, contact your physician.

Table 6. Troubleshooting messages

Message	Solution
Strength is OFF The generator could not deliver the desired strength. Contact your clinician if the problem persists.	Try adjusting strength again. If you continue to encounter this problem, contact your physician.
Unsupported Device This application is not compatible with this device.	Use the device provided by St. Jude Medical.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Cannot locate patient controller app.	Patient controller app is not on patient controller Home screen.	Swipe through screens from the patient controller Home screen to locate app. Search for the app using iOS software search functionality.
Patient controller has no power or has lost power.	Patient controller's battery is drained.	Recharge the battery using the charger.
	Patient controller is damaged or malfunctioning.	Replace the patient controller.
Patient controller will not charge.	Charger is disconnected from the patient controller.	Connect the charger to the patient controller.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
	Correct plug adapter (voltage converter) is not connected to the charger.	Connect the appropriate plug adapter (voltage converter) to the charger.
	Charger is defective.	Replace the charger.
	Patient controller is damaged or malfunctioning.	Replace the patient controller.
Nothing is displayed on the screen.	Patient controller is off or has timed out.	Turn on the patient controller.
	Patient controller's battery is drained.	Recharge the battery using the charger.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
	Screen is damaged or malfunctioning.	If the patient controller appears to be powered on but without display, the screen may be defective. Contact Technical Support.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Patient controller will not respond to input.	Patient controller has locked up.	Perform a soft reset. 1. Press and hold the Power button until the *slide to power off* bar appears. 2. Slide the bar to the right. 3. Press and hold the Power button until the Apple™ icon appears.
	Touch-screen interface is damaged or malfunctioning.	Replace the patient controller.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Patient controller is not communicating with the generator.	Patient controller is off or has timed out and is in standby mode.	Wake up the patient controller.
	Patient controller battery is drained.	Charge the patient controller battery.
	Bluetooth wireless technology connection is not strong or turned off.	Decrease the distance between the devices. Move the devices away from other devices that may be causing interference.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		Move the devices so they share line of sight. Do not operate other wireless devices at the same time. Wait a few minutes and try connecting again. Turn Bluetooth wireless technology on using the instructions in the "Troubleshooting messages" table.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
	Patient controller is damaged or malfunctioning.	Replace the patient controller.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local St. Jude Medical representative.

Appendix A: Downloading the Patient Controller App

When you receive your patient controller, you need to download the patient controller app so you may use it with your generator. The patient controller app is compatible with the Apple™ iPod touch™ mobile digital device provided by St. Jude Medical. (iPod touch™ is a trademark of Apple Inc.)

If you do not have an Apple™ ID you may create one while setting up the device or before installing the app. If you have already set up your patient controller, see the steps below for downloading the app.

To create a new Apple ID:

1. Make sure the device is connected to a Wi-Fi network.
2. Follow the onscreen prompts.

   NOTE: Use an existing e-mail address or set up a free iCloud™ e-mail address. Note your password since you will need it to verify your account and update your app. (iCloud™ is a trademark of Apple Inc.)
3. Click **Verify now** in the e-mail sent to your e-mail address.
4. Follow the onscreen prompts to finish creating your Apple ID.

To download the app:

1. Make sure the device is connected to a Wi-Fi network.
2. Tap the App Store icon on the patient controller Home screen of your device.
3. Enter **St. Jude Medical** in the Search field.

4. Once you locate the correct app, follow the onscreen prompts.

   NOTE: If you do not have an Apple ID, create one using the onscreen prompts and the instructions above.

   NOTE: If you encounter problems downloading the app, contact Technical Support.

Appendix B: Pairing the Patient Controller to the Generator

The following instructions outline the steps for pairing the patient controller to the generator.

1. Place the magnet perpendicular to the generator for 10 seconds.
2. Tap the patient controller app.

   The patient controller app launches.
3. Tap +.

   The Add Generator screen opens.
4. Tap an available generator in the "Select a Generator…" list.

   If no generators are found, you will see the No Generators Found message. Tap ↻ to search for available generators again and refresh the generator list.

5. Enter the pin code displayed on the screen in the Bluetooth Pairing Request dialog box.
6. Tap **Pair** to pair the patient controller and generator.

   The "Connecting to Generator…" message displays while the patient controller is connecting to the generator.

Appendix C: Regulatory Statements

NOTE: These statements are applicable to the generator. For Regulatory Statements regarding the patient controller, refer to the Apple™ manual available at http://www.apple.com/support/ipodtouch/.

Statement of FCC Compliance

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

equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

Operation is subject to the following two conditions:

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

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

Statement of Compliance With License-Exempt RSS Standard (Canada)

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Declaration of Conformity (Industry Canada) Notice to Users of Radio and Television

This Class B digital apparatus meets all the requirements of the Canadian interference-causing equipment regulations.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format:

Table 8. St. Jude Medical Infinity™ Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	RIASJMRFC
Industry Canada (IC) Registration Number	8454A-M3660123

Product Classification Statement (CISPR 11, Class B)

This product is class B equipment, which is intended primarily for use in the domestic environment.

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® Smart wireless technology as it is implemented in the device.

Table 9. Bluetooth Smart wireless technology information

Antenna type	Embedded patch antenna in header
Antenna dimensions	8.1 mm x 5.1 mm x 4.9 mm
Modulation	GFSK
Magnetic field strength (at 2 m distance)	16.3 µA/m
Electric field strength (at 2 m distance)	6.1 mV/m
Output power (EIRP*)	1 mW (0 dBm) typical, 10 mW (+10 dBm) maximum
Range	1–2 m typical
Center frequency	2.44 GHz
Channel	40 logical channels
Bandwidth	2 MHz per channel
Data flow	Bi-directional

Table 9. Bluetooth Smart wireless technology information

Protocol	Bluetooth Smart wireless technology
*EIRP = Equivalent isotropically radiated power	

Radio Transmitter, Cables, Transducers

The device contains a radio transmitter/receiver with the following parameters.

Radio transmitter parameters:

- Frequency (range): 2.4000 to 2.4835 GHz
- Bandwidth (-15dB): 2.398 to 2.4855 GHz
- Channel: 40 logical channels using AFH
- Modulation: GFSK
- Radiated output power: 10 mW (+10 dBm) maximum
- Magnetic field strength (at 2 m distance): 16.3 µA/m
- Duty cycle: Variable, but low (<5%)
- Semi-duplex capability

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.

Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Smart wireless technology enables communication between the generator and the patient controller. The quality of the wireless communication link varies depending on the use environment (operating room, recovery room, and home environment).

After the patient controller is paired with a generator, the Bluetooth wireless technology symbol is visible on the patient controller in the upper right-hand corner of the screen. When the Bluetooth Smart wireless technology connection is not active, the symbol appears dimmed.

The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is

resent if not successfully received. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (i.e., if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (e.g., the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, please refer to "Troubleshooting for Wireless and Coexistence Issues" (page 78).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator will encrypt its wireless communication.
- Only one patient controller may communicate with the generator at the same time.
- A unique key for each unit that is checked during each transmission.
- Built-in pairing that specifies valid and legitimate pairing among units.
- Proprietary authentication in addition to the pairing procedure specified in Bluetooth® Smart wireless technology, which includes an element of proximity.

- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the generator.

Troubleshooting for Wireless and Coexistence Issues

If you experience issues with the wireless communication between the generator and the patient controller, try the following:

- Decrease the distance between the devices
- Move the devices so they share line of sight
- Move the devices away from other devices that may be causing interference
- Close the patient controller application and turn the patient controller off and on
- Wait a few minutes and try connecting again
- Do not operate other wireless devices (i.e., laptop, tablet, mobile phone, or cordless phone) at the same time

  NOTE: Wireless communications equipment, such as wireless home network devices, mobile and cordless telephones, and tablets, can affect the device.

Appendix D: Electromagnetic Compatibility Guidelines

The generator, 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 has no essential performance, as defined by IEC 60601-1 Edition 3.1:2012. Performance of the device was maintained during immunity 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 60601-1-2:2007-03, IEC 60601-1-2:2014-04, EN 55011:2009/A1:2010 (CISPR 11:2010), and ETSI EN 300 328 V1.8.1 (2012-06).

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 St. Jude Medical-approved components with this system. Do not use St. Jude Medical components with other non-St. Jude Medical devices or systems.

Table 10. Guidance and manufacturer's declaration – electromagnetic emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy for 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	

Table 11. 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 earth	Not applicable	No guidance for battery-powered devices.
Voltage dips, short interruptions IEC 61000-4-11	<5% U_T 40% U_T 70% U_T	Not applicable	No guidance for battery-powered devices.

Table 11. Guidance and manufacturer's declaration – electromagnetic immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
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	6 Vrms 150 kHz to 80 MHz 6 Vrms (ISM/Radio bands between 150 kHz to 80 MHz) 80% AM at 1 kHz	6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Table 11. Guidance and manufacturer's declaration – electromagnetic immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Recommended separation distance $d=0.58\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	20 V/m	Recommended separation distance $d=0.18\sqrt{P}$ 80 to 800 MHz $d=0.35\sqrt{P}$ 800 MHz to 2.5 GHz

Table 11. Guidance and manufacturer's declaration – electromagnetic immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

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

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.

Table 12. 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 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	

Table 12. Guidance and manufacturer's declaration – proximity fields

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
	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 EPG, including cables specified by St. Jude Medical. Otherwise, performance degradation may occur.

NOTE: For the frequency bands in the table above, use the specified recommended separation distance. The recommended separation distances in the table below apply to all other frequencies within the specified ranges.

Table 13. Recommended separation distances between portable and mobile RF communications equipment and the device

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	80 to 800 MHz $d=0.18\sqrt{P}$	800 MHz to 2.5 GHz $d=0.35\sqrt{P}$
0.01	0.1	0.0	0.0
0.1	0.2	0.1	0.1
1	0.6	0.2	0.4
10	1.8	0.6	1.1
100	5.8	1.8	3.5

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

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

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

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

Radio Frequency Information

The effective radiated power is below the limits as specified in:

- USA: FCC 47 CFR Part 15:2012
- Canada: RSS-210 Issue 8
- Europe: ETSI EN 301 489 V1.9.2, ETSI EN 301 489-1 and ETSI EN 301 489-17

  NOTE: Maintain a reasonable distance between other electronic equipment and the device.

  CAUTION: The ISM band used by this device has been approved by the Federal Communications Commission for unlicensed use. However, there is no guarantee that this device will not receive interference or that any particular transmission from this device will be free from interference.

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