Implantable Pulse Generator

Proclaim™ IPG

Clinician's Manual

St. Jude Medical

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

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

Contents

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use

This neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

Contraindications

This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

Warnings

The following warnings apply to these components.

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

Magnetic resonance imaging (MRI). Patients with an implanted neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off.

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

Implanted cardiac systems. 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.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Device components. The use of non-St. Jude Medical components with this system may result in damage to the system and increased risk to the patient.

Case damage. Do not handle the IPG if the case is pierced or ruptured because severe burns could result from exposure to battery chemicals.

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

Precautions

The following precautions apply to these components.

General Precautions

Clinician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient selection. It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system.

Infection. Follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

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

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the IPG and proceed with caution, being sure to move through the detector quickly.

Mobile phones. The effect of mobile phones on neurostimulation systems is unknown; patients should avoid placing mobile phones directly over the system.

Sterilization and Storage

Single-use, sterile device. The implanted components of this neurostimulation system are intended for a single use only. 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 sterile field. Do not resterilize or reimplant an explanted system for any reason.

Storage environment. Store components and their packaging where they will not come in contact

with liquids of any kind.

Handling and Implementation

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

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

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

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

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

Hospital and Medical Environments

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

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

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

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

Adverse Effects

In addition to those risks commonly associated with surgery, the following risks are associated with implanting or using this IPG:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off your IPG immediately.)
- Stimulation in unwanted places
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the IPG site
- Seroma (mass or swelling) at the IPG site
- Allergic or rejection response to implant materials
- Implant migration or skin erosion around the implant
- Battery failure

Product Description

This implantable pulse generator (IPG) is an electronic device designed to be connected to one or

more extensions or leads with up to 16 electrodes total. It is powered by a hermetically sealed battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation. The IPG can deliver stimulation with a single program or with multiple programs. Each program can provide stimulation to a single anatomical area or to multiple areas. The IPG communicates wirelessly with system programmers and controllers, and IPGs are available in small and large sizes to accommodate different power needs. Some models can receive software upgrades after implantation to provide patients with additional features as approved by the respective regulatory agencies. To upgrade features on the IPG, a system programmer is needed.

For more information about IPG features and specifications, see the appropriate appendix in this manual.

> **NOTE:** For more information about the neurostimulation system, see the clinician's programming manual for this system.
> **NOTE:** In this document, the term "clinician programmer" refers to the St. Jude Medical™ Clinician Programmer device, "patient controller" refers to the St. Jude Medical Patient Controller device, "clinician programmer app" refers to the St. Jude Medical Clinician Programmer software application (app), and "patient controller app" refers to the St. Jude Medical Patient Controller app.

Package Contents

In addition to the product documentation, the IPG kit contains the following items:

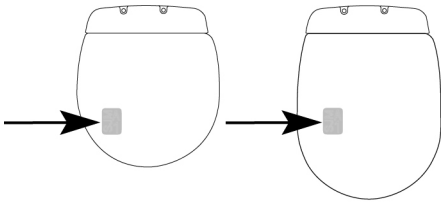
- 1 IPG (see the appendix in this manual for model numbers)
- 1 pocket sizer
- 1 torque wrench (Model 1101)
- 2 port plugs (Model 1111)

Identifying the IPG

Before implanting the IPG, you can view the model number engraved on the IPG. After implantation, you can identify the IPG using a radiopaque identification tag that you can view with standard X-ray procedures. The tag, which is located in the lower left corner of the IPG when the logo side of the IPG is facing toward you, contains a code in the following format: SJM*LN*. SJM designates St. Jude Medical as the manufacturer; *LN* is a letter and a number combination that identifies the model family (see the following figure).

For the Proclaim™ IPG, the code is SJM A1. To determine the exact model IPG that is implanted, use the clinician programmer app to communicate with the IPG and view IPG information. See the clinician's manual for the clinician programmer for instructions.

Figure 1. Location of the IPG code on a small IPG (left) and large IPG (right)



Directions for Use

Read this section carefully for suggested directions for use related to the IPG. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

NOTE: Before the surgical procedure, set up communication between the clinician programmer and the IPG while the IPG is in its sterile packaging to ensure that it is functional. If the IPG has never established communication with a programmer, you must first activate the IPG for communication ("wake up" the IPG) by holding a magnet over the IPG for 8 seconds.

Creating an IPG Pocket

The following steps outline the suggested procedure to create an IPG pocket:

1. Determine the site for the IPG, ensuring that the lead is long enough to reach the pocket and provide a strain relief loop.

   NOTE: The IPG should be located in an area that the patient can easily reach with the programming wand. Common sites for implantation are: along the midaxillary line, in the upper buttock along the posterior axillary line (taking care to avoid the belt line), and in the area over the abdomen just below the lowermost rib. To ensure a flat area is selected, you can mark a flat area prior to the surgical procedure while the patient is in a sitting position.

   CAUTION: Do not place the IPG deeper than 4.0 cm (1.57 in) because the clinician programmer may not communicate efficiently with the IPG.
2. Create the pocket so that the IPG is parallel to the skin surface and no deeper than 4.0 cm (1.57 in) below the skin surface.
3. Insert and remove the pocket sizer to ensure that the pocket is large enough to accommodate the IPG, allowing enough extra room for a strain relief loop for each lead or extension.

Connecting a Lead or Extension to the IPG

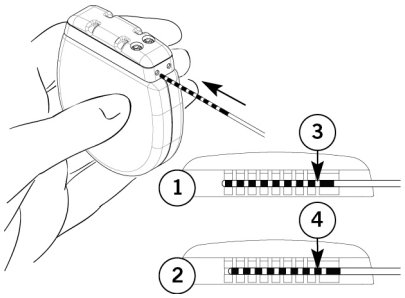
The following steps outline the suggested guidelines to connect a lead or extension to the IPG:

CAUTION: Do not connect a lead or extension with body fluid or saline residue on its contacts because corrosion can occur and cause failure of the system.

1. If any of the lead or extension contacts came in contact with body fluid or saline, thoroughly clean the contacts with sterile deionized water or sterile water for irrigation and dry them completely.

   CAUTION: Observe these cautions when performing the following step:
   - **Do not bend the lead sharply or it may be damaged.**
   - **Do not loosen the setscrew in the connector more than a quarter turn at a time while trying to insert the lead. Retracting the setscrew too far can cause the setscrew to come loose and make the connector assembly unusable.**
2. Using clean gloves, carefully slide the proximal end of the lead or extension into the IPG header until it stops. When the lead or extension is correctly inserted, the contact bands on the lead or extension are fully inside the connector assembly and the windows between each of the header contacts are clear.

Figure 2. Insert the lead or extension fully into the IPG header

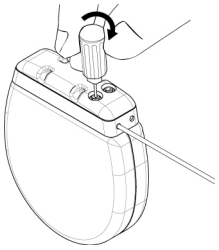


1. Fully inserted
2. Not fully inserted
3. Window between each header contact is clear
4. Window between each header contact is partially blocked by contact band

CAUTION: Use only the torque wrench that is compatible with the IPG or the device may be damaged and rendered unusable.

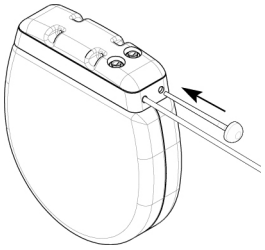
3. Insert the torque wrench through the septum and tighten the setscrew, turning it clockwise until the wrench clicks.

Figure 3. Tighten the setscrew clockwise



4. Remove the torque wrench and check the septum to ensure that it closed. If the septum did not close, gently reseat the septum flaps.
5. If implanting two leads, repeat the previous steps. If implanting a single lead only, insert the header port plug into the unused port, and use the torque wrench to tighten the setscrew until it clicks.

Figure 4. Insert the port plug



Implanting the IPG

The following steps outline the suggested procedure to implant the IPG:

1. Place the IPG into the IPG pocket with the logo side facing the skin surface and at a depth not to exceed 4.0 cm (1.57 in).

   NOTE: By implanting the IPG with the logo side facing the skin surface, you enhance the IPG's ability to detect a magnet.

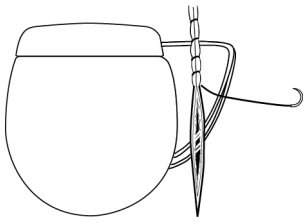
Figure 5. Place the IPG in the pocket

2. Carefully coil any excess lead or extension behind the IPG in loops no smaller than 2.5 cm (1 in) in diameter to provide strain relief for the lead or extension and IPG connection.
   CAUTION: Do not bring the suture needle in contact with an IPG, lead, or extension, or the component may be damaged.
3. To stabilize the IPG within the pocket, pass suture through the holes at the top of the IPG header and secure it to connective tissue.
4. Check the entire system by fluoroscopy before closing to ensure proper positioning of the lead or leads and that it is straight, with no sharp bends or kinks.
5. Use the clinician programmer app to communicate with the IPG and perform intraoperative testing to confirm that the system is operational. See the clinician's manual of the clinician programmer app for instructions.

   NOTE: IPG output may not be identical to that of the trial stimulator at the same settings.
6. Ensure that the IPG is away from the pocket incision suture line, close the pocket incision,

and apply the appropriate dressings.

Figure 6. Close the pocket incision



Replacing the IPG

The following steps outline the suggested procedure to replace an IPG:

1. Turn off the IPG or verify that it is turned off.
   CAUTION: Exercise care when using sharp instruments or electrocautery around leads or extensions, or they may be damaged.
2. Open the IPG implant site per normal surgical procedure.
3. Insert the torque wrench through the septum of the IPG header and loosen the setscrew by turning it counterclockwise.
   CAUTION: When performing the following step, do not bend the lead or extension sharply; or it may be damaged.
4. Gently remove the lead or extension from the IPG header; then clean and dry all connections, ensuring they are free of fluid and tissue.
5. To complete the IPG replacement procedure, see the following sections: “Connecting a Lead or Extension to the IPG” (page 5) and “Implanting the IPG” (page 7).

Disposing of Explanted Components

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 Technical Support.

Checking the Status of the IPG Battery

The IPG contains a nonrechargeable battery. The amount of time that the battery will provide active stimulation depends on the patient’s stimulation settings and daily usage time. To check the status of the IPG battery, use the clinician programmer app or patient controller app. The clinician programmer app can also estimate how much time remains until the IPG battery can no longer support stimulation. For more information about these functions, refer to the clinician’s programming manual and the user’s guide for the patient controller app. For more information about the estimated longevity of the IPG battery, see the product specifications in the appropriate appendix in this manual.

NOTE: For more accurate measurements of the end of the IPG battery’s life, wait at least 8 days after initial communication between the IPG and the clinician programmer app.

The following information provides general guidelines for the battery status:

- The battery status icon on the clinician programmer app or patient controller app shows a decreasing fill as the batteries are used.
- A warning will appear on the clinician programmer app or patient controller app when the battery is critically low.
- Stimulation will automatically stop when the battery cannot support stimulation.

Technical Support

For technical questions and support for your St. Jude Medical™ neuromodulation product, use the following information:

- +1 972 309 8000
- +1 800 727 7846 (toll-free within North America)

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

Appendix A: Product Specifications

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Storage Specifications

Store the components according to the following conditions.

Table 1. Storage conditions for components

Temperature	-20°C–60°C (-4°F–140°F)
Humidity	10%–90% (noncondensing)
Pressure	70–150 kPa (10.2–21.8 psi)

Product Materials

Table 2. Product materials for IPG kit

Component	Material
IPG	Titanium, silicone rubber
Pocket sizer	Polybutylene terephthalate
Port plug	Polysulfone

IPG Specifications

The Proclaim™ IPGs have the following physical specifications.

Table 3. IPG specifications

Model			**MRI Status**	**Upgradeable Features**
	3660	3662	Untested	Yes
	3665	3667	Untested	No
Height	5.55 cm (2.19 in)	6.68 cm (2.63 in)		
Length	4.95 cm (1.95 in)	5.02 cm (1.98 in)		
Thickness	1.34 cm (0.53 in)	1.35 cm (0.53 in)		
Weight	48.9 g (1.7 oz)	58.3 g (2.1 oz)		
Volume	30.4 cm^3 (1.9 in^3)	38.6 cm^3 (2.4 in^3)		
Estimated battery longevity (nominal settings)*	4.5 years	6.5 years		
Power source	Carbon monofluoride/silver vanadium oxide cell			
Connector strength	Exceeds EN 45502-1 requirements			
Program storage capacity	16 programs with 8 stim sets each			
* Battery longevity was estimated using the following nominal settings 12 hours per day: 50-Hz frequency, 225-µs pulse width, and 5-mA amplitude at 500-ohms impedance. For information on how additional settings may impact the longevity of the device, please contact Technical Support.				

The IPG has the following operating parameters.

Table 4. Operating parameters for the IPG

Parameter	Tonic Range	Steps	Burst Range	Steps
Pulse width	20–1000 µs	10 µs (20–500 µs range) 50 µs (500–100 µs range)	20–1000 µs	50 µs
Frequency	2–200 Hz	2 Hz	—	—
	200–500 Hz	10 Hz	—	—
	500–1200 Hz	20 Hz	—	—
Burst rate frequency	—	—	10–60 Hz	10 Hz

Parameter	Tonic Range	Steps	Burst Range	Steps
Intraburst frequency	—	—	250–500 Hz	10 Hz
			500–1000 Hz	20 Hz
Amplitude	0–25.5 mA	0.1–1.0 mA	0–12.75 mA	0.05–1.0 mA

NOTE: The number of stim sets in use for a tonic program governs the maximum frequency (1200/number of stim sets).

NOTE: The maximum current depends on the impedance, frequency, and pulse width settings.

Appendix B: System Components and Accessories

The Proclaim™ neurostimulation system includes the following components.

NOTE: Not all models are available in all countries. Contact your local representative for more information.

IPGs

3660 Proclaim™ 5 Elite IPG

3662 Proclaim™ 7 Elite IPG

3665 Proclaim™ 5 IPG

3667 Proclaim™ 7 IPG

IPG Accessories

1101 Torque wrench

1111 Port plug

Programmers and Controllers

3874 St. Jude Medical™ Clinician Programmer App

3875 St. Jude Medical™ Patient Controller App

Programmer and Controller Accessories

1210 Patient magnet

3884 SCS patient manual and magnet

Leads and Extensions

3100-series percutaneous leads

3200-series paddle leads

3300-series extensions

Lead and Extension Accessories

1100-series stylets

1102 Guide wire for percutaneous leads

1103 Introde-AK™ lead introducer

1105 Lead anchor, butterfly

1106 Lead anchor, long

1109 Strain relief

1112 Tunneling tool, 12 in
1114 Epidural needle, 14 gauge, 4 in (10 cm)
1116 Epidural needle, 14 gauge, 6 in (15 cm)
1120 Tunneling tool, 20 in
1192 Swift-Lock™ anchor
1194 Cinch™ anchor
1701 SCS accessory kit

Trial System

3599 St. Jude Medical™ External Pulse Generator

Trial System Accessories

1203 Cleaning cloths
1212 Coin cell batteries
1213 Pouch with adhesive (5)
1214 Pouch without adhesive and belt (5)
1216 EPG header cap
1218 Carrying case
1917 Battery door
3014 Multilead trial cable
3032 External pulse generator, 2-port header

Appendix C: Regulatory Statements

This section contains regulatory statements about your product.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device 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.

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.

Identification Information for Product Registration

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

Table 5. Registration identification information

Identifier Type	Registration Identifier
FCC registration number	RIASJMRFC
Industry Canada (IC) registration number	IC: 8454A-M3660123

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® low energy (BLE) technology as it is implemented in the device.

Table 6. Bluetooth low energy 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
Protocol	BLE
*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® low energy (BLE) wireless technology enables communication between the generator and the patient controller. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, and home environment).

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

Other requirements include 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 sent successfully. Each key press may transmit up to 8 data packets, 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).

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 or clinician programmer 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 low

energy, 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 clinician programmer or 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
- 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: Symbols and Definitions

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

Symbol	Description
	Caution, Consult Accompanying Documents
	Consult instructions for use
	Follow instructions for use on this website
	Denotes that the device contains a radio-frequency (RF) transmitter, which may cause RF interference with other devices near this device.
	Denotes single use only
	Do not resterilize
	Denotes expiration date
	Denotes date of manufacture
	Denotes temperature limits for storage conditions
	Denotes humidity limits
	Denotes pressure limits
	Do not use if the product sterilization barrier or its packaging is compromised

Symbol	Description
REF	Catalog number
	Manufacturer
	Contents quantity
PN	Code that uniquely identifies an inventory item
SN	Serial number
LOT	Batch code
℞ ONLY	Prescription only
STERILE EO	Ethylene oxide gas sterilization
EC REP	Authorized European representative
CE 0086 0168	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC and R&TTE directive 1999/5/EC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these directives.
	Complies with AS/NZS standards: AS/NZS 4268 (Australia and New Zealand)
R-NZ	Complies with New Zealand's Radiocommunications (Radio Standards) Notice 2010 in accordance with section 133 of the Radiocommunications Act 1989 and regulation 32 of the Radiocommunications Regulations 2001
	Complies with Japanese radio standard ARIB T-66 V3.6

Additional Symbols for Product Labels

Symbol	Description
Torque Wrench	Torque wrench
Port Plug	Port plug
Implantable Pulse Generator	Implantable pulse generator

Appendix E: CE Mark Date

Table 7. Year in which CE mark was awarded

Model	Year
1101	1999
1111	2006
3660, 3662, 3665, 3667	2015

Manufacturer:
St. Jude Medical
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Plano, Texas 75024
USA
+1 972 309 8000

Manufacturing Site:
St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5
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St. Jude Medical
Coordination Center BVBA
The Corporate Village
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Manufacturing Site:
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Australian Sponsor:
St. Jude Medical Australia Pty. Limited
17 Orion Road
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ST. JUDE MEDICAL™

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