Securing the EPG

The following steps outline the suggested guidelines for securing the EPG to the patient:

1. Place the EPG into the provided pouch.
2. Remove the adhesive liner on the pouch flap.
3. Use the flap to secure the leads in place and seal the pouch.

   NOTE:
   The EPG meets the IP22 rating when sealed in the pouch.

4. Remove the adhesive liner on the back of the pouch and press the pouch onto the patient's skin until it is secure.

   NOTE:
   It is good practice to secure the EPG pouch away from the lead entry site bandaging.

   NOTE:
   Leave some slack in the leads or extensions when securing the EPG onto the patient.

5. Use additional medical tape to secure the pouch and leads or extensions further as needed.

Programming the EPG

Use the clinician programmer app to program the system for the trial period. For information on using the clinician programmer app for programming, refer to the clinician's programming manual.

Caring for the EPG

The EPG is an important part of the neurostimulation system. This section provides tips and other information about caring for the EPG.

Handling the EPG

- Do not expose the EPG to prolonged direct sunlight.
- Avoid exposing the EPG to sand, dust, and other environmental hazards.
- Do not put heavy or sharp objects on the EPG.
- Keep the EPG away from food and beverages, and avoid getting the EPG wet.
- If the EPG does get wet, do not use it. Contact Customer Service at +1-972-309-8000 for help.

Cleaning the EPG

- Using two PDI Sani-Cloths, wipe the EPG for 2 minutes front and back, then allow to air dry. Once the EPG is dry, attach the header cap.

NOTE:
Clean the EPG before attaching the header cap.

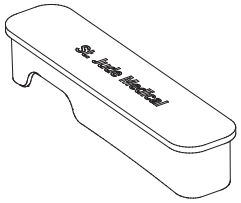
- Clean the EPG by thoroughly wiping off its outer surface using the provided cleaning cloths. Do not wipe over the stimulator port. Do not submerge the EPG or use a cloth that is soaking wet.
- Never use ammonia, acidic, or alkaline cleaners or organic chemicals such as paint thinner, acetone, propyl alcohol, or kerosene. They may damage surface finishes of the EPG.

Storing and Transporting the EPG

- Store the EPG and batteries in a cool, dry place. Do not store the EPG or batteries in your car or garage.
- Transport the EPG in a carrying case.
- If you are carrying the EPG in a briefcase or other carrying case, make sure no objects in the case are pressing on the device.
- Store paired EPGs and patient controllers together to reduce the number of times you need to set up communication.
- At the end of a trial, disable stimulation, clean the EPG, and attach the header cap before storing the EPG.

NOTE:
During a trial store the header cap for reuse.

Figure 11. EPG header cap



Service and Ordering Information

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

Customer Service Information

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

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

EC REP

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

Ordering Information

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

Table 1. Ordering information for the EPG

Model	Description
3599	EPG kit
3032	Header Accessory kit
1212	Coin cell batteries
1917	Battery door
3013	MLTC
1210	Magnet
1203	Box of cleaning cloths
1216	EPG header cap
1213	Pouch with adhesive (5)
1214	Pouch without adhesive and belt (5)
1218	Carrying case

Appendix A: Product Specifications

EPG with Header

The EPG (Model 3599) and EPG header (Model 3032) has the following physical specifications.

Table 2. EPG and EPG header specifications

Height	79.8 mm (3.14 in)
Width	57.2 mm (2.25 in)
Thickness	11 mm (0.433 in)
Weight (with batteries)	44 g (1.55 oz)
Volume	44.57 cc (2.72 cu in)
Power source	Nonrechargeable CR2450 coin cell
Lead or extension compatibility	2 octrode
Expected service life	5 years
Storage temperature	-25°C - 70°C (-13°F - 158°F)
Operating temperature	5°C - 40°C (41°F - 104°F)
Storage humidity	up to 93% (noncondensing)

Operating humidity	15% - 93% (noncondensing)
Storage pressure	70 - 106 kPa (10.2 - 15.4 psi)
Operating pressure	70 - 106 kPa (10.2 - 15.4 psi)

Table 3. Operating parameters for the EPG

	Tonic Range	Steps	Burst Range	Steps
Pulse width	50 - 500 µs	12 - 13 µs	50 - 1000 µs	50 µs
Frequency	2 - 200 Hz 200 - 500 Hz 500 - 1200 Hz	2 Hz 10 Hz 20 Hz	—	—
Burst rate frequency	—	—	10 - 60 Hz	10 Hz
Intra-Burst frequency	—	—	250 - 500 Hz 500 - 1000 Hz	10 Hz 20 Hz
Amplitude	0 - 25.5 mA (max 12 V)	0.1 - 1.0 mA	0 - 12.75 mA	0.05 - 1.0 mA

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

Appendix B: Regulatory Statements

Declaration of Conformity

Hereby, St. Jude Medical declares that this medical device is in compliance with the essential requirements and other relevant provisions of AIMD directive 90/385/EEC. For a copy of the declaration of conformity, please contact Customer Service by mail at 6901 Preston Road, Plano, TX 75024, USA, or by telephone at +1 972 309 8000.

Battery Disposal Guidelines

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.

Antenna Guidance Statement (Canada)

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be chosen so that the equivalent isotropically radiated power (EIRP) is not more than that necessary for successful communication.

Statement of Compliance With Interference-Causing Equipment Standard (Canada)

This ISM device complies with Canadian ICES-001.

Identification Information for Product Registration

On the exterior of this equipment is a label that contains, among other information, a product identifier in the following format:

Table 4. Registration identification information

Identifier	Description
FCC Registration Number	PX2SJMX599EPG
Industry Canada (IC) Registration Number	8454A-SJMX599EPG

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 summarized the technical details of the Bluetooth® low energy technology as it is implemented in the device.

Table 5. Bluetooth low energy information

	Bluetooth low energy
Antenna type	Embedded ceramic antenna
Antenna dimensions	4 mm x 3 mm x 1.1 mm

Modulation	GFSK
Magnetic Field Strength (at 10 m distance)	0.000145 A/m maximum
Electric Field Strength	0.055 V/m maximum
Output power (EIRP*)	1 mW (0 dBm) typical, 10 mW (+10 dBm) maximum
Range	2 meters typical
Center frequency	2.44 GHz
Channel	40 logical channels
Bandwidth	2 MHz per channel
Data-rate	5 kbit/second
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: 0.000145 A/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 wireless technology enables communication between the EPG and the clinician programmer or 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 clinician programmer or patient controller is paired with a generator, (Bluetooth symbol) is visible on the clinician programmer or patient controller in the upper right-hand corner. When the BLE connection is not active, the symbol is grayed out.

The raw BLE data rate is approximately 2.5 KB/sec and the effective data rate is approximately 1.5 - 2 KB/sec. 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 C: Electromagnetic Compatibility Guidelines

The EPG, 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 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, 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 6. 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 7. 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	No guidance for battery-powered devices.
Surge IEC 61000-4-5	±1 kV line to 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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 8. Guidance and manufacturer's declaration – electromagnetic immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	20 V/m	the transmitter. Recommended separation distance d=0.18√P 80 to 800 MHz d=0.35√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

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.

Table 9. Guidance and manufacturer's declaration – electromagnetic immunity (conducted RF and radiated RF)

Immunity Test	IEC 60601 Test Level	Immunity Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device than the recommended separation distance.

Immunity Test	IEC 60601 Test Level	Immunity Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ (80 MHz to 800 MHz) $d=2.3\sqrt{P}$ (800 MHz to 2.5 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

NOTE: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength of 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 re-orienting or relocating the device.

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

Table 10. 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 $d=0.17\sqrt{P}$	80 to 800 MHz $d=0.18\sqrt{P}$	800 MHz to 2.5 GHz $d=0.35\sqrt{P}$

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d=0.17\sqrt{P}$	80 to 800 MHz $d=0.18\sqrt{P}$	800 MHz to 2.5 GHz $d=0.35\sqrt{P}$
0.01	0.12	0.02	0.04
0.1	0.37	0.06	0.11
1	1.16	0.18	0.35
10	3.67	0.55	1.11
100	11.6	1.75	3.5

NOTE: Wireless communications equipment, such as wireless home network devices, mobile and cordless telephones, and walkie-talkies, can affect the device. Keep the device away from wireless 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.

Appendix D: Symbols and Definitions

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

Symbol	Description
	Caution, Consult Accompanying Documents
	Denotes that the user must consult this document for important safety-related information (This symbol is blue and white on the device.)
	Consult instructions for use
	Denotes device contains a type BF applied part to protect you from shock. The device is internally powered and is intended for continuous operation.
	Denotes that the device contains a radio-frequency (RF) transmitter, which may cause RF interference with other devices near this device.

Symbol	Description
	Denotes to keep the device dry
IP22	Ingress protection rating for a device that is protected from the intrusion of solid foreign objects as small as 12.5 mm in diameter and is protected from vertically dripping water when the device is tilted at an angle up to 15 degrees
	Denotes single use only
	Denotes date of manufacture
REF	Catalog number
	Manufacturer
UNIT	Denotes content, the number of items contained in the package
PN	Code that uniquely identifies an inventory item
SN	Serial number

Symbol	Description
LOT	Lot number
UDI	Unique device identification number
Rx only	Prescription use only
	Denotes that this product shall not be treated as household waste. Instead it is the user's responsibility to return this product to St. Jude Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact St. Jude Medical.
EC REP	Authorized European representative
CE	European conformity
0123	The EU notified body number for AIMD

Symbol	Description
	This device is listed by Nationally Recognized Testing Laboratory (NRTL) as certified.
	Denotes compliance with AS/NZS standards: AS/NZS 4268:2003

Appendix E: CE Mark Date

Table 11. Year in which the CE mark was awarded.

Model	Year
3599	2014

St. Jude Medical, Inc.
Global Headquarters
One St. Jude Medical Drive
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