

St. Jude Medical™ External Pulse Generator
Model 3599

CLINICIAN'S MANUAL





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

Unless otherwise noted, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL and the nine-squares symbol are trademarks and service marks of St. Jude Medical, Inc. and its related companies. © 2014 St. Jude Medical, Inc. All Rights Reserved.

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

Contents

Prescription and Safety Information.....	1
Intended Use	1
Indications for Use	1
Contraindications.....	1
Warnings	2
Precautions.....	3
Adverse Effects	5
Product Description	6
Overview of the EPG and EPG Header	8
Package Contents.....	9
Getting Started.....	10
Overview of the EPG Procedure.....	10
Replacing the EPG Batteries	11
Checking the Status of the EPG Batteries	16
Setting Up Communication Between the EPG and the Clinician Programmer and Patient Controller.....	17
EPG Indicator Light.....	18

Starting and Stopping Stimulation	18
Using the EPG	21
Connecting the Multilead Trial Cable to the EPG	21
Disconnecting the Multilead Trial Cable from the EPG	23
Securing the Leads or Extensions	24
Connecting the EPG Header to the EPG	24
Connecting the Leads or Extensions to the EPG Header	25
Securing the EPG	28
Programming the EPG	29
Caring for the EPG	29
Handling the EPG	29
Cleaning the EPG	29
Storing and Transporting the EPG	30
Service and Ordering Information	31
Customer Service Information	32
Ordering Information	33
Appendix A: Product Specifications	34
EPG with Header	34
Appendix B: Regulatory Statements	36
Declaration of Conformity	36

Battery Disposal Guidelines.....36
Statement of FCC Compliance.....37
Statement of Compliance With License-Exempt RSS Standard (Canada).....38
Antenna Guidance Statement (Canada)38
Statement of Compliance With Interference-Causing Equipment Standard (Canada)38
Identification Information for Product Registration38
Product Classification Statement (CISPR 11, Class B).....39
Wireless Technology Information39
Radio Transmitter, Cables, Transducers40
Quality of Service for Wireless Technology.....41
Appendix C: Electromagnetic Compatibility Guidelines 44
Appendix D: Symbols and Definitions 54
Appendix E: CE Mark Date..... 57



Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The St. Jude Medical trial stimulator is intended to be used externally with St. Jude Medical-approved trial leads and extensions to deliver stimulation to one or more neurological structures for a maximum of 30 days.

Indications for Use

The St. Jude Medical™ trial 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 neurostimulation system is contraindicated for patients who are unable to use the system. Neurostimulation should not be used on patients who are poor surgical risks, such as those with multiple illnesses or active general infections.

Warnings

The following warnings apply to these components.

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

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 device. Contact between an active electrode and an implanted lead or extension can cause direct stimulation of the tissue at the electrode site and cause severe injury to the patient. If use of electrocautery is necessary, first turn off the neurostimulation system.

Implanted cardiac system. 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 functions of the implantable cardiac system.

Magnetic resonance imaging (MRI). Patients with an EPG should not be subjected to MRI.

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.

System 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.

Power supply. Use only the CR2450 batteries supplied with the device. CR2450 batteries have a nominal voltage of 3V and nominal capacity of at least 600 mAh.

Precautions

The following precautions apply to these components.

General Precautions

Clinician Training. Clinicians should be experienced in implanting neurostimulation devices and should

have undergone sufficient 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 and inform patients to avoid showering and touching the bandages.

Handling and Implementation

Single use only. The EPG header is intended for single use only.

Exposure to liquids. Device components should be stored where they will not be exposed to liquids or excessive moisture, which can damage the package materials and components.

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

Package or component damage. Do not use the device if the package or components show signs of damage. Return any suspect components to St. Jude Medical for evaluation.

System testing. To ensure correct operation, the system should always be tested 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.

Component disposal. Dispose of the EPG header and pouch with other medical waste. Return the EPG to St. Jude Medical for safe disposal when necessary.

Hospital and Medical Environments

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of a 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, disconnect the EPG from the leads or extensions. Damage to the system may not be immediately detectable.

Adverse Effects

The use of a neurostimulation system involves risks. In addition to those risks commonly associated with surgery, the following risks are also associated with use of a neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off stimulation on your EPG immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places

- Allergic or rejection response to device materials

Product Description

The St. Jude Medical™ External Pulse Generator (EPG) is an external trial generator that when connected to trial neurostimulation leads delivers therapeutic stimulation to parts of the body. The EPG communicates wirelessly with system programmers and controllers.

The EPG header connects directly to the EPG for a neurostimulation trial. The EPG header can hold one or more leads or extensions with up to 16 electrodes total.

NOTE:

For more information about the neurostimulation system, see the clinician's programming manual for this system.

NOTE:

The EPG is supplied nonsterile and is intended to be used multiple times. The EPG header is also supplied nonsterile, but is single use only.

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 app, and "patient controller app" refers to the St. Jude Medical™ Patient Controller app.

Overview of the EPG and EPG Header

Refer to the following figures for the EPG and EPG header features:

Figure 1. EPG features

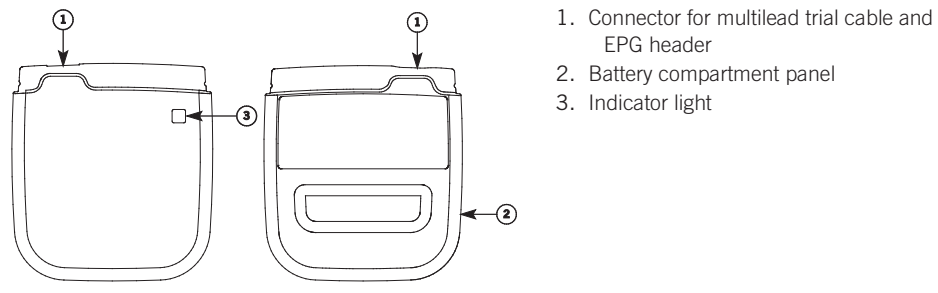
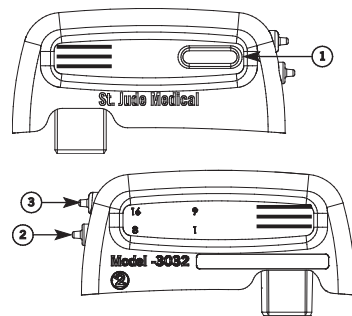


Figure 2. EPG header features



1. Button
2. Port 1, electrodes 1-8
3. Port 2, electrodes 9-16

Package Contents

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

- 1 EPG (Model 3599)
- 1 EPG header cap

- 1 battery door

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

- 1 EPG header
- 2 CR2450 Batteries
- Cleaning cloths
- 1 EPG pouch with adhesive
- 1 magnet (Model 1210)

Getting Started

This section provides a general overview of the EPG procedure and instructions for tasks, such as replacing the batteries and setting up communication between the EPG and the clinician programmer and patient controller.

Overview of the EPG Procedure

The following steps provide a general overview of the EPG procedure. Refer to the following sections for more information about each of these steps.

1. Replace the EPG batteries.
2. Set up communication between the EPG and the clinician programmer and patient controller.
3. Implant the leads or extensions.

4. Connect the leads or extensions to the multilead trial cable.
5. Connect the multilead trial cable to the EPG.
6. Test the system.
7. Disconnect the multilead trial cable from the EPG.
8. Disconnect the multilead trial cable from the leads or extensions.
9. Secure the leads or extensions and bandage the lead entry site.
10. Connect the EPG header to the EPG.
11. Insert the leads or extensions into the EPG header.
12. Place the EPG into the pouch and secure to the patient.
13. Program the system.

Replacing the EPG Batteries

The EPG uses two nonrechargeable CR2450 coin cell batteries. St. Jude Medical recommends replacing the batteries before starting a new trial and only using the batteries included in the Header Accessory kit.

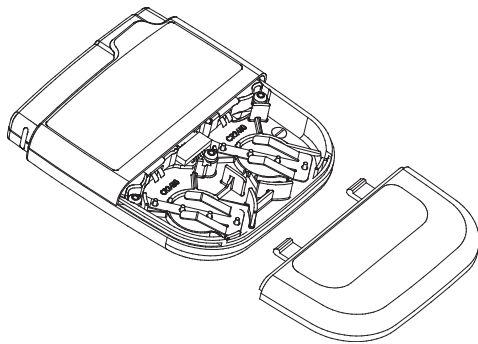
NOTE:

Dispose of batteries safely. Do not treat them as household waste. Refer to the guidelines in Appendix B for more information.

To replace the batteries, follow these steps:

1. Disconnect the EPG header or multilead trial cable from the EPG if either is connected. Also, if the EPG is communicating with the clinician programmer or patient controller, end the session. Refer to the clinician's programming or user's controller manual for instructions.
2. Press and slide the battery compartment panel outward to open the battery compartment and remove the panel.

Figure 3. Battery compartment panel

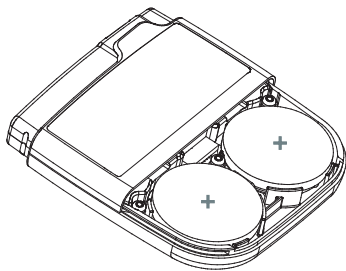


3. Remove the batteries by either:
 - turning the EPG over so the battery compartment is facing down and lightly tapping the EPG in the palm of your hand, or
 - pressing down on one side of the battery so the opposite side pops up, lifting the battery out,

and repeating the process with the remaining battery.

4. Insert a new battery into the battery compartment, paying attention to the polarity directions provided on the inside of the battery compartment.
5. Insert the second battery into the second battery compartment.

Figure 4. Inserting batteries into the battery compartment



6. Place the battery compartment panel flush to the EPG, lining up the tabs with the coordinating

indentation.

Figure 5. Replacing the battery compartment panel



7. Slide the panel closed flush with the EPG until it snaps into place.

NOTE:

When you insert the batteries, the indicator light is solid. You must wait until the indicator light is flashing or off to set up communication.

NOTE:

If you replace the batteries but the generator battery indicator on the clinician programmer app or patient controller app indicates the batteries are low, make sure the batteries are inserted correctly.

Checking the Status of the EPG Batteries

Check the status of the EPG's batteries using the clinician programmer app or the patient controller app. Refer to the clinician's programming or user's controller manual for these directions.

NOTE:

Battery life depends on usage and stimulation settings, with batteries lasting at least 14 days under nominal or practical high output tonic settings, with 500 ohm impedance and stimulation on for 16 hours per day. (High output is based on actual patient use collected in St. Jude Medical clinical studies, not the maximum device output.)

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 batteries are critically low.
- Stimulation will automatically turn off when the batteries cannot support stimulation. Replace the EPG's batteries to communicate with the EPG, turn stimulation on, change stimulation settings, or retrieve stimulation usage information.

NOTE:

If the batteries deplete during a trial, instruct the patient to refrain from replacing the batteries to avoid disturbing the bandaging and lead position.

Setting Up Communication Between the EPG and the Clinician Programmer and Patient Controller

Before starting the surgical procedure, set up communication between the EPG and the clinician programmer and patient controller. The following steps outline the procedure for setting up communication. For further instructions, refer to the clinician's programming manual.

1. Place the magnet perpendicular to and centered directly over the front of the EPG for 10 seconds. The indicator light on the EPG will start flashing.
2. Set up communication using the clinician programmer app or the patient controller app following the directions shown on the screen.

After setting up communication, the EPG is paired with that clinician programmer and patient controller. You will not need to pair them again unless another patient controller or more than four clinician programmers are paired to the EPG.

NOTE:

Store paired EPGs and patient controllers together to reduce the number of times you need to set up communication.

EPG Indicator Light

The indicator light on the EPG will flash for the following reasons:

- When batteries are inserted into the EPG
 - When a communication session with the clinician programmer app or patient controller app is started
 - When the magnet is held for approximately 10 seconds over the EPG (signaling the EPG is ready to pair with the clinician programmer or patient controller)
-

NOTE:

The EPG indicator light flashes faster when it is ready to pair than when batteries are inserted or a communication session is started.

Starting and Stopping Stimulation

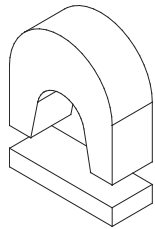
Use the clinician programmer app or the patient controller app to start or stop stimulation. The magnet included with the EPG system may also be used to start or stop stimulation if the Magnet Mode is

programmed to On/Off or Off.

To use the magnet, follow these steps:

1. Take the keeper bar off the magnet.

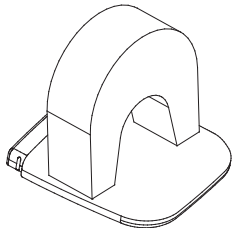
Figure 6. Magnet and keeper bar



1. Magnet
 2. Keeper bar
-

2. Hold the magnet perpendicular to and centered directly over the EPG for 2 seconds.

Figure 7. Holding the magnet over the EPG



-
3. Remove the magnet, replace the keeper bar, and store the magnet.

CAUTION:

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

Using the EPG

Read this section for directions for use related to the EPG and EPG header. For directions for use of other system components not covered in this document, see the clinician's manual for the appropriate device.

NOTE:

Well in advance of the surgical procedure, set up communication between the EPG and the programmer and controller to ensure it is functional. Refer to "Setting Up Communication Between the EPG and the Clinician Programmer or Patient Controller" for instructions.

CAUTION:

Before the EPG or associated components are used or secured to the patient, determine if a patient may have an allergic reaction to the materials.

Connecting the Multilead Trial Cable to the EPG

The following information outlines the guidelines for connecting a multilead trial cable to the EPG. For further instructions, refer to the clinician's manual for the multilead trial cable.

1. Remove the EPG header cap to expose the EPG stimulator port.
2. Carefully slide the connector end of the multilead trial cable into the EPG stimulator port.

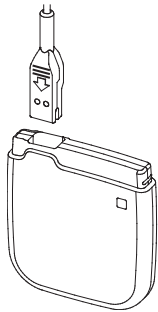
CAUTION:

The EPG is not sterile. When connecting and testing the EPG with the multilead trial cable, keep the EPG outside of the sterile field.

CAUTION:

To avoid delivering jolting stimulation to the patient, turn off stimulation before plugging in the multilead trial cable.

Figure 8. Inserting the connector into the EPG stimulator port



Disconnecting the Multilead Trial Cable from the EPG

The following steps outline the guidelines for disconnecting the multilead trial cable from the EPG. For further instructions, refer to the clinician's manual for the multilead trial cable.

1. Turn off stimulation on the EPG using the clinician programmer app.

2. Grasp the connector end of the multilead trial cable and gently pull the connector from the EPG stimulator port.

Securing the Leads or Extensions

The following information outlines the suggested procedure for securing the leads or extensions to the patient:

- Secure the leads or extensions and bandage the lead entry site. For further instructions, refer to the clinician's manual for the applicable leads or extensions.

Connecting the EPG Header to the EPG

The following information outlines the guidelines to connect the EPG header to the EPG:

- Align the tab indentation on the EPG header with the tab on the EPG and carefully insert the EPG header into the EPG body until it clicks into place.

Figure 9. Connecting the EPG header to the EPG



Connecting the Leads or Extensions to the EPG Header

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

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:

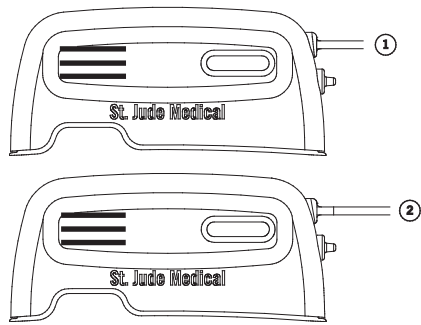
Do not bend the lead sharply or it may be damaged.

NOTE:

The EPG header comes with open ports and attached port plugs. Do not remove the port plugs from the header. If only using one lead or extension, use the lower port labeled 1-8 and insert a port plug in the unused port.

2. Push and hold the button on the EPG header to open the EPG header ports.
3. Using clean gloves, carefully slide the lead or extension into the EPG header until you reach a hard stop and all the contact bands are fully inside the connector assembly and hidden from view.

Figure 10. Insert the lead or extension fully into the EPG header



1. Fully inserted
2. Not fully inserted

4. Release the button to lock the lead or extension into place.
5. If applicable, repeat the previous steps to insert the remaining lead or extension. Do not disturb the already inserted lead or extension.