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1. WELCOME

Congratulations on joining the Pulsante® family! Please read this Manual before using your Pulsante® SPG Microstimulator System. Here you will find instructions on using your Remote Controller to deliver therapy, as well as tips on storage and warnings and precautions. These instructions are intended for patients who have been prescribed a Pulsante® SPG Microstimulator System by their doctor.

2. INTENDED USE OF THE PULSANTE® SPG MICROSTIMULATOR SYSTEM

In the United States, the Pulsante® SPG Microstimulator System is intended to relieve the acute pain of cluster headache.

3. SYMBOLS

Symbols and definitions used for the Pulsante® SPG Microstimulator System:

	For Prescription Use Only
	Consult Operating Instructions
	Model Number
	Serial Number
	Lot Number
	Content
	Use Only With
	Peel Apart
	Warning/Precaution
	Storage and Transport Temperature Range
	Keep Dry
	Manufactured By
	Do Not Do the following



Do not dispose devices in unsorted trash. Dispose devices per local country regulations for disposing electrical equipment



Do not use device if package is opened or damaged



Date of Manufacture



Use By Date

Symbols and definitions used only for the Pulsante® Microstimulator:



Electrode



Channel



Constant Current



Length



Max Implant Depth



Sterilized using Ethylene Oxide



Content of unopened, undamaged package is sterile



Single Use



The Pulsante® Microstimulator is MR Unsafe.

Symbols and definitions used only for the Pulsante® Remote Controller:



Non-Ionizing Radiation



Power ON/OFF button symbol



Up Button symbol



Down Button symbol



Applied Type B Equipment



USB connector symbol



The Pulsante® Remote Controller is MR Unsafe. It will be hazardous in all MRI environments.



Press Up or Down Button symbol



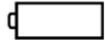
Searching For Microstimulator antenna symbol



Recharge Remote symbol



Low Battery symbol



Depleted Battery symbol



Battery Charging symbol



Fully Charged Battery symbol



Alert Indicator symbol

Symbols and definitions used only for the Pulsante® Surgical Tools:



Single Use Only



Sterilized using Ethylene Oxide

Symbols and definitions used for the Pulsante® Programmer Software on Clinician Programmer:



Tilt Symbol indicates that the selected stimulation amplitude is not being delivered



Power ON/OFF button symbol

4. PULSANTE® SPG MICROSTIMULATOR SYSTEM OVERVIEW

The rechargeable Pulsante® SPG Microstimulator System (the “System”) electrically stimulates the sphenopalatine ganglion (SPG) peripheral nerve structure in your face (behind the nose). The rechargeable System includes a miniaturized Pulsante® Microstimulator, which is placed at the SPG through an incision in your gum (Figure 1). The Pulsante® Microstimulator has six electrodes, which are programmed by your doctor using the proprietary Pulsante® Programmer Software to customize therapy to your individual needs. The Microstimulator is then controlled and powered by a Pulsante® Remote Controller. You can use the Remote Controller to treat your headaches as needed. Periodically, the Remote Controller battery needs recharging using the Remote Controller Charger provided.

Figure 1: Location of the Implanted Pulsante® Microstimulator



Figure 2: Pulsante® Remote Controller

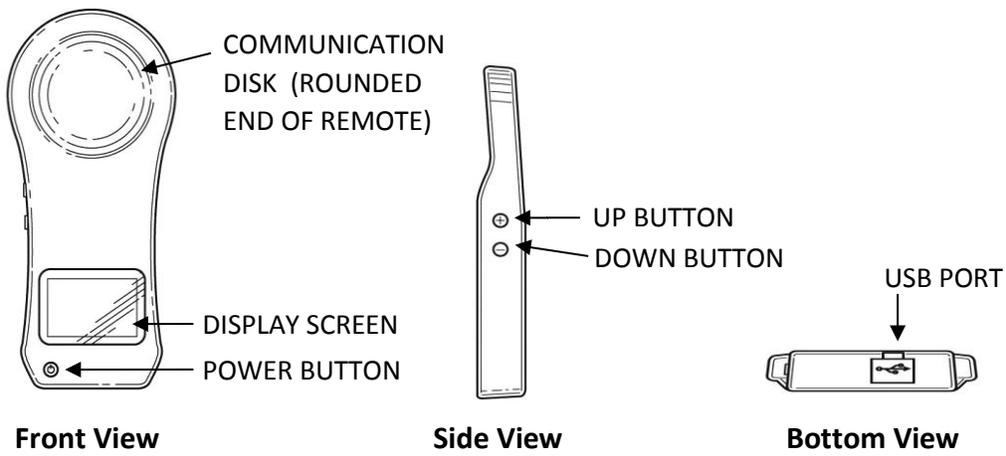


Figure 3: Pulsante® Microstimulator

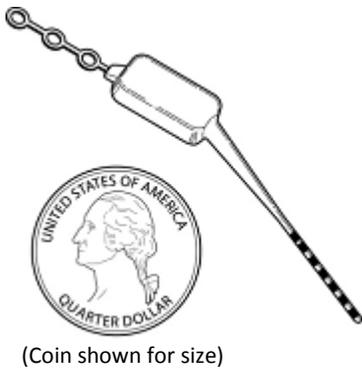
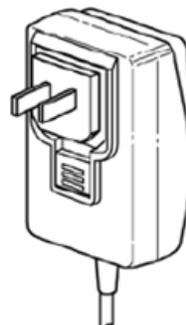


Figure 4: Remote Controller Charger



5. PULSANTE® SPG MICROSTIMULATOR SYSTEM CONTRAINDICATIONS

The Pulsante® SPG Microstimulator System should not be used in patients who have an opening to the pterygopalatine fossa of less than 1.2mm or have had metal implants or facial surgery in an area that would prevent proper placement of the Microstimulator.

6. WARNINGS & PRECAUTIONS

WARNINGS

Carefully read all instructions prior to use. Observe all warnings and precautions noted in this Manual.

Diathermy

Diathermy is the use of high-frequency electromagnetic currents as a form of physical therapy in surgical procedures. Do Not undergo shortwave diathermy, microwave diathermy, or therapeutic diathermy. Diathermy may cause damage to the tissue near your Microstimulator.

Magnetic Resonance Imaging (MRI)

Because a number of things affect MRI compatibility, your safety and the effectiveness of your therapy after your Microstimulator has been exposed to MRI is unknown. MRI uses strong energy that may interact with your Microstimulator and injure tissue near your Microstimulator. You should not undergo MRI until you have talked with your doctor.

Procedures of the Pterygopalatine Fossa

The SPG is located within a space behind your nose called the pterygopalatine fossa. This is where part of your Microstimulator is implanted. The effects of other procedures on the Microstimulator in this area are not known. Permanent damage to the Microstimulator may result from these procedures. Procedures in this area include intra-nasal thermocoagulation and procedures to the SPG, maxillary branch of the trigeminal nerve, vidian nerve or other neurovascular structures. NOTE: Inform your doctor of the implanted Microstimulator before undergoing any procedure in the pterygopalatine fossa.

Electrical Therapies and Diagnostic Imaging

The effects of certain electrical therapies and diagnostic imaging on the Microstimulator are not well understood. If you require such treatment, your doctor should consult Autonomic Technologies for current information on how electrical therapies and diagnostic imaging could affect your device. Electrical therapies and diagnostic imaging include, but are not limited to: nuclear imaging (for example, PET Scans), brachytherapy, therapeutic radiation stereotactic radiosurgery, electroconvulsive therapy, lithotripsy, therapeutic ultrasound, transcranial magnetic stimulation, bone growth stimulators, and electrolysis. Do Not use your Remote Controller to apply therapy while undergoing any electrical therapy or diagnostic imaging procedure.

Explosive or Flammable Gases

Do Not use your Remote Controller in an environment where explosive or flammable gases are present.

Other Medical Devices

Do Not place the Remote Controller over other implantable devices (for example, pacemaker, defibrillator, another neurostimulator). The Remote Controller may accidentally change the operation

of another device. Do not place another device's transmitter over the Microstimulator. It may accidentally disrupt the operation of the Microstimulator.

Exposure to Moisture

Do Not use your Remote Controller to activate your Microstimulator while showering, swimming, or during other activities where the Remote Controller may get wet. The Remote Controller is not waterproof and should be kept dry to avoid damage.

PRECAUTIONS

Doctor Instructions

Always follow your doctor's instructions. Failure to do so may cause the therapy to be less effective in providing headache relief.

Pulsante® SPG Microstimulator System Failure

Although it is unlikely, the System may unexpectedly malfunction, as does any implantable electronic device. Autonomic Technologies has completed extensive testing under worst-case conditions to develop and manufacture high-quality devices. However, malfunctions may be caused by things that cannot be predicted and may result in the device not working and the need for additional surgery. If a malfunction occurs, then your Remote Controller may not be able to wirelessly connect with your Microstimulator or your Microstimulator may not deliver therapy.

Lack of Therapy

The communication between the Remote Controller and the Microstimulator is based on many factors, including orientation and distance between the two devices. Swelling near the incision and/or implant location may prevent communication between the Remote Controller and the implanted Microstimulator, and therapy may not be possible. Your doctor will adjust your device settings over time to optimize therapy based on your anatomy and device placement. If you have any difficulty getting the Remote Controller to wirelessly connect with the Microstimulator, please consult your doctor or consult the Troubleshooting section of this manual.

Device Migration

While unlikely, the "lead" of your Microstimulator (the part that contains the electrodes and sits near your SPG) may move from its desired location. Lead movement may change how well your therapy works. If lead movement does occur, additional surgery may be needed. To help minimize the chance of lead migration, care should be taken (particularly in the two weeks after the Microstimulator surgery) not to put excess pressure on the implant location.

Long-Term Stimulation

The effects of long-term SPG stimulation are not known. If you experience any unusual symptoms that you think may be related to your Microstimulator, contact your doctor. If you or your doctor decide that the System is not providing the therapy you need, it may be left implanted and not used for stimulation or will require additional surgery to be explanted.

Prior Surgical Procedures

Alert your doctor if you have had a previous facial or skull surgery. If any metal objects have been implanted in your face, these implanted objects may interfere with the System. Prior surgeries in these areas may also affect the position of the Microstimulator. Tooth fillings will not interfere with the System.

Post-Implant Medical Tests and Procedures

Before you undergo any medical tests or procedures, you should contact your doctor to determine if the procedure will cause damage to your System. The following procedures or tests should only be performed and the following devices should only be used after talking to your doctor: facial nerve blocks (for example, infra-orbital or maxillary), orthodontic or dental procedures, and cosmetic procedures.

Therapeutic Radiation

Therapeutic radiation may damage the electronic circuitry of the System. Sources of therapeutic radiation include, but are not limited to: therapeutic x-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted device should be shielded with lead.

Implantable and External Devices

How your System works with other medical devices, including pacemakers, defibrillators, neurostimulators, hearing aids and other implantable and external devices, is not well understood. If you require such a device, your doctor should consult Autonomic Technologies for current information concerning the use of these devices.

Cardiac Defibrillation/Cardioversion

The effect of internal or external defibrillation or cardioversion on your implanted Microstimulator is not known. If you undergo defibrillation, see your doctor to confirm your Microstimulator settings before using your Remote Controller.

Electromagnetic Interference (EMI)

If you approach certain commercial electrical equipment (for example, arc welders, induction furnaces, resistance welders), communication equipment (for example, microwave programmers, linear induction motors, linear power amplifiers, high-power amateur transmitters, and cellular phones), and high-voltage power lines too closely, it may generate sufficient EMI to cause paresthesia (a sensation of tingling, pricking or numbness in the face) or interfere with your System. If you are uncomfortable or unable to apply therapy when you are near such equipment, move away from the area of EMI. The system has been designed to fail safely so strong EMI could prompt your Remote Controller to turn off.

Interaction with Electronic Systems

How your System interacts with other electronic devices including RFID systems (particularly within the 121 kHz to 130 kHz range) is not fully understood. Do not use your remote controller close to other electronic devices, particularly keyless entry FOBs or near automobile electronics. The strong electromagnetic fields from the remote controller can disrupt electronic systems that are close by.

Interaction with Metallic or Magnetic Objects

Using the System close to metal or magnetic objects (for example, heavy metal jewelry, metal headphones, magnetic earrings) may prevent your Remote Controller from communicating properly with your Microstimulator, especially if that metal object is between your Remote Controller and your cheek. If you are unable to apply therapy when you are near such objects, move away from the object and try again. Metallic objects in the mouth (for example, a metal retainer) may get warm if they are not removed prior to applying therapy. For clarification, your Remote Controller is safe to use with tooth fillings.

Handling of the Pulsante® Remote Controller

Use care when handling your Remote Controller. The Remote Controller is a sensitive electronic device that may be damaged by rough handling, including dropping on the ground or being crushed. Store the Remote Controller in a cool, dry place. Excess heat can reduce the battery life of the

Remote Controller considerably (for example, do not leave the Remote Controller in your car or under direct sunlight for long periods of time).

Charging the Pulsante® Remote Controller

Only use the Charger provided in the Remote Controller packaging to charge the Remote Controller. Use of non-Pulsante® charging equipment to charge the Remote Controller can damage your Remote Controller.

Scuba Diving or Hyperbaric Chambers

Yes, you can enjoy swimming and diving with your Microstimulator. However, you should not dive below 30 meters (98 feet) of water or enter hyperbaric chambers above 4.0 atmospheres absolute (ATA), as greater pressures may damage your Microstimulator. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor. And, remember to leave your Remote Controller in a dry place—do not use the Remote Controller while swimming or diving.

Excess Pressure or Trauma

You can enjoy a wide variety of sports with your Microstimulator. However, you should avoid putting excess pressure on your Microstimulator and avoid trauma to that area. Playing certain contact sports (for example, boxing) may damage your System or change how well it works with your headaches. If you experience excess pressure or trauma to the area around your Microstimulator, contact your doctor.

Pregnancy

The safety and effectiveness of this therapy have not been established for pregnancy, unborn fetus, or delivery.

Pediatric

The safety and effectiveness of this therapy have not been established for patients under the age of 22.

7. RISKS AND SIDE EFFECTS

Please discuss the risks and benefits with your doctor to determine if the device is right for you. Risks of neurostimulation therapy can include surgical risks, possible side effects, or device complications. Your doctor can provide more information about these and other potential risks. Please follow your doctor's instructions after surgery to minimize surgical risk.

Similar to other oral procedures, most patients will experience some or all of the following effects post-surgery and most effects resolve within 60 days:

- Sensory and/or motor dysfunction, including numbness, other sensations, and/or facial paresis (slight or incomplete paralysis)
- Post-operative pain, swelling and/or tenderness at the surgery site

Other risks of surgery may include:

- Seroma/Hematoma (a collection of serum/blood in the body)
- Abscess
- Bruising
- Permanent numbness and other sensations
- Dry eye and tearing

- Trismus (lockjaw)
- Itching
- Pain in the area of the implant
- Infection
- Bleeding
- Facial asymmetry
- Allergic response to implanted materials
- Headache
- Penetration of the sinus wall
- Increased severity/frequency of cluster headaches
- Post-operative nausea or emesis (vomiting)
- Nose bleed
- Ear or nasal fullness/rhinorrhea (nasal discharge)
- Taste alteration

Possible side effects of SPG stimulation include:

- Discomfort or pain during stimulation associated with paresthesia (a sensation of tingling, pricking or numbness in the face)
- Runny nose
- Dry eye and tearing
- Conjunctivitis
- Headache

Device complications may include:

- Microstimulator migration or misplacement potentially leading to explant and/or re-implant
- Inability of the Remote Controller to connect with the Microstimulator
- Device malfunction
- Skin and/or bone erosion around the Microstimulator implant site

8. PACKAGING, STORAGE AND HANDLING

- The Remote Controller can be safely stored and operated between +5°C and +40°C. The Remote Controller can be transported between -20°C and +70°C. Temperatures outside of this range may reduce battery life.
- Please treat your Remote Controller with care. It is a sensitive electronic device that may be damaged by rough handling, including dropping on the ground or being crushed.
- Do not sterilize the Remote Controller.
- Do not store the Remote Controller where it may become wet, as moisture may damage the package materials or the Remote Controller.
- Do Not use the Remote Controller if the packaging or the Remote Controller looks damaged.
- Do not connect the USB Port to any other electrical device; use only the Charger provided with the Remote Controller.
- The Remote Controller may feel warm when providing therapy. If experiencing discomfort, move the Remote Controller away from the face slightly and avoid contact with skin.
- The Remote Controller should not come into contact with skin that is cut or bleeding.

9. PATIENT USE INSTRUCTIONS: HOW TO OPERATE YOUR REMOTE CONTROLLER

Getting Started

It is important to follow your doctor's instructions for taking any medication, including antibiotics and to report any side effects from the surgery or therapy to your doctor. Following your surgery, your doctor will work with you to treat your headaches. Your doctor will use a Remote Controller to communicate with your Microstimulator. Your doctor will set the maximum therapy level that you will be able to use with your Remote Controller. During stimulation, you may feel a mild tingling feeling. The Microstimulator cannot provide therapy without the Remote Controller. You will be given a Remote Controller to use at home to treat your headaches. Unless your doctor tells you differently, you can use your Remote Controller with the Microstimulator as often as is needed.

Using the Pulsante® Remote Controller to Apply Therapy

1. To turn on your Remote Controller, push and release the orange Power button.
2. The screen will turn on and display a symbol prompting you to press the blue Up or Down button. Press either the Up or Down button (Figure 5).
3. After pressing the blue Up or Down button, the Remote Controller will begin to vibrate and display a blinking antenna symbol, which means that it wirelessly searching for your Microstimulator (Figure 6).
4. Hold the Remote Controller to your cheek so the Communication Disk is over the location of your implanted Microstimulator (Figure 7).
5. Adjust the position of the Communication Disk by tilting it or moving it to different positions on your face until your Remote Controller stops vibrating. Therapy will begin when the Remote Controller stops vibrating.
6. When the Pulsante® Remote Controller stops vibrating, the therapy will slowly increase from zero to the level set by your doctor.
7. If the Remote Controller loses its wireless connection with your Microstimulator, then the Remote Controller will begin to vibrate. Simply adjust the Communication Disk position over your cheek until the vibration stops.
8. You can press the blue Down button at any time to stop the therapy from increasing further and remain at the level you choose. At any time during therapy, you can change the therapy level using the Up and Down buttons:
 - a. Press the Down button to decrease the amount of therapy.
 - b. Press the blue Up button to increase the amount of therapy until you reach an adequate level of pain relief. The Remote Controller will not exceed the maximum amount of therapy set by your doctor. If you are already at maximum therapy and press the blue Up button, your Remote Controller will make a short vibration to let you know that you are already at the maximum.
9. If your Remote Controller starts to heat up, please move your Remote Controller away from your face; wait for the Remote Controller to cool before re-applying therapy.
10. When finished, remove the Remote Controller from your cheek and press the orange Power button.

Figure 5: Remote Controller Screen When Ready to Start

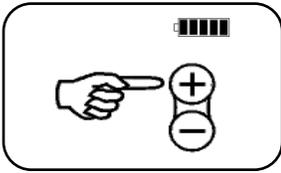
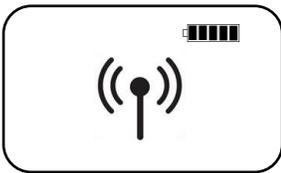


Figure 6: Remote Controller Screen When Searching for Your Microstimulator



NOTE: Therapy is only provided when the Communication Disk is held over your Microstimulator and the Remote Controller is **NOT** vibrating.

NOTE: The Remote Controller will search for the Microstimulator for approximately one (1) minute. If the Microstimulator is not located, the Remote Controller will turn OFF and the screen will go blank. You may turn your Remote Controller ON (step 1 above) if you wish to continue searching for your Microstimulator to apply therapy.

Figure 7: Use of the Remote Controller (with Communication Disk on Cheek Above Microstimulator)



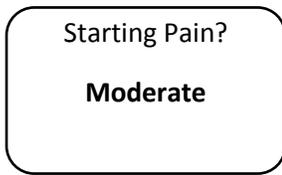
NOTE: You can also remove the Remote Controller from your cheek at any time to stop therapy.

NOTE: Keep your Remote Controller nearby at all times so that you can apply therapy when needed.

Using the Headache Diary

If your doctor has activated the headache diary in your Remote Controller, then the questions your doctor selected will appear after you finish therapy and press the orange Power button. For each question, use the blue Up and Down buttons to choose from the list of answers, then press the orange Power button to select and save your answer. Your Remote Controller will turn off when you finish the diary questions.

Figure 8: Example Headache Diary Question Screen



Charging the Pulsante® Remote Controller

The Remote Controller Display Screen will tell you how much battery power remains. Make sure the Remote Controller is charged often. To increase the life of the Remote Controller, charge the Remote Controller daily as you would a cell phone. Only use the Charger provided in the Remote Controller packaging to charge the Remote Controller. Do not use any other Charger to charge the Remote Controller. When the Remote Controller power is low, the battery level indicator will show a low battery and an electrical plug (Figure 9), prompting you to plug in the Remote Controller. If the power level continues to decline, the screen will display a depleted battery indicator (Figure 10). When the depleted battery indicator is blinking, the Remote Controller will not be able to provide therapy until it is charged.

Figure 9: Low Battery Indicator

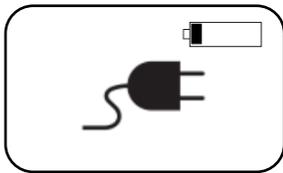
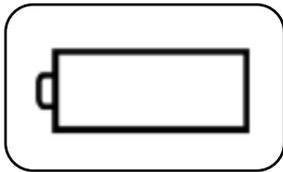


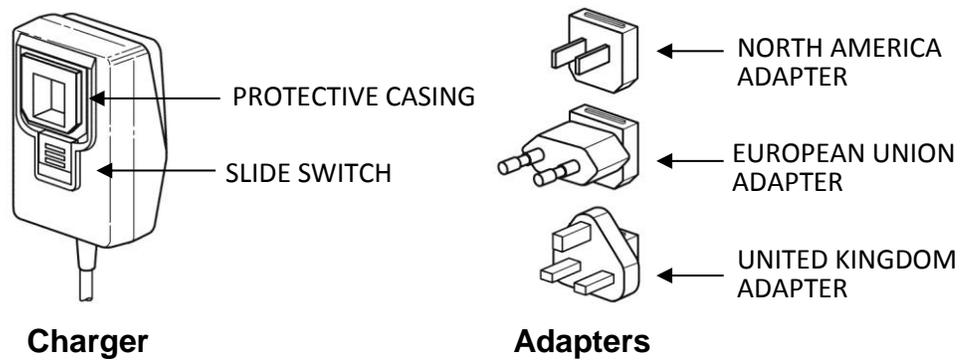
Figure 10: Depleted Battery Indicator



NOTE: If the Remote Controller batteries are low, further application of the therapy may not be possible.

A Charger is provided with your Remote Controller (Figure 11). The Remote Controller does not have replaceable batteries. Do not attempt to open the Remote Controller. An Adapter is provided with the Charger for use in North America. While traveling in the European Union or United Kingdom, use the additional adapters that are included to accommodate those power outlets.

Figure 11: Charger and Adapters



Follow these instructions to set up and use the Charger:

- Remove the protective casing by pushing the Slide Switch down (Figure 12).
- Connect the North American Adapter to the Charger (Figure 13).
- To change Adapters, remove the existing Adapter by pushing the Slide Switch down and removing the Adapter. Next, push the Slide Switch down and insert the next Adapter into the Charger.
- Insert the charger into the USB Port on your Remote Controller (Figure 14)
- Plug the charger into the power socket.

Figure 12: Removing the Protective Case

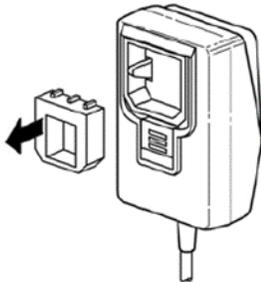


Figure 13: Connecting an Adapter to the Charger (United States Adapter Shown)

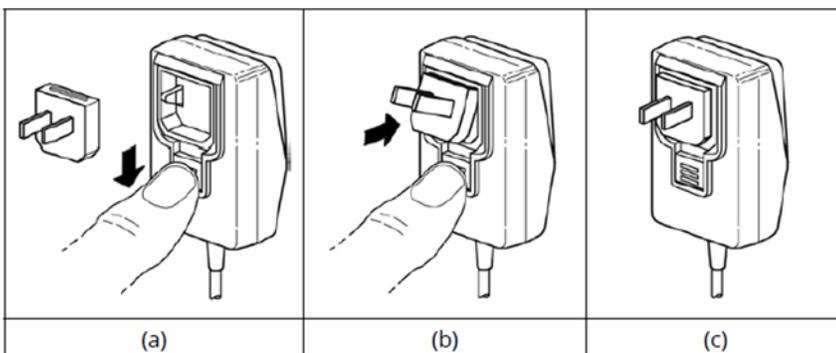


Figure 14: Orientation of the Charger's USB Plug and the Remote Controller



Figure 15: Connecting the USB Plug End



Figure 16: Remote Controller Display Screen When Charging

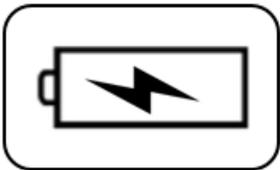
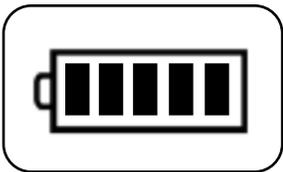


Figure 17: Remote Controller Display Screen When Fully Charged



Ensure that the correct Adapter is properly inserted into the Charger prior to inserting the Charger into the power socket. Keep the Charger away from children.

NOTE: If needed, the Remote Controller when fully charged can be used to provide therapy continuously for up to 2 hours before it runs out of power. Please ensure that the Remote Controller is sufficiently charged (at least 2 battery bars) prior to using it again for subsequent therapies.

Cleaning and Caring for the Pulsante® Remote Controller

Follow these steps to ensure that your Remote Controller functions properly:

- Use the Remote Controller only as instructed by your doctor and this manual.

- Handle the Remote Controller with care. Avoid dropping, striking, or stepping on the Remote Controller.
- Do not take apart or tamper with the Remote Controller.
- Clean the outside of the Remote Controller using an alcohol wipe (such as a Walgreens® 70% Isopropyl Alcohol Wipe) when needed. Do not clean it with bleach, nail polish remover, mineral oil, or similar substances.
- The Remote Controller is Not waterproof. Do not immerse the Remote Controller in liquids or allow liquids to enter inside the Remote Controller.

When the Pulsante® Remote Controller Should NOT Be Used

- Do Not use your Remote Controller when explosive or flammable gases or liquids are present.
- Do Not use the Remote Controller if it breaks open or gets dismantled or damaged.
- Do Not use your Remote Controller while showering, while bathing, while swimming, or during other activities where the Remote Controller may get wet.

Using Household Appliances

It is safe to use pagers, computers, headphones, Bluetooth headsets, microwave ovens, electric toothbrushes, electric razors and standard household appliances with your Microstimulator and the Remote Controller.

Traveling with Your Pulsante® Microstimulator — Theft Detectors and Security Devices

Yes, you can travel by plane! With the Microstimulator, you may pass through theft detectors or security devices as needed. This includes metal detectors and full body x-ray screening machines (such as those found in airports or libraries). Your Remote Controller may be placed on an X-ray conveyer belt for X-ray screening. The System has also been tested according to FAA specifications to ensure it is safe to use while on an airplane. Yes, you can use it while flying. NOTE: Operating the System close to security screeners, metal detectors, or anti-theft devices may prevent your Remote Controller from working properly with your Microstimulator. If you are unable to apply therapy when you are near such objects, move away from the object and try again.

Disposal of the Pulsante® Remote Controller and/or Charger

If the Remote Controller and/or Charger stops working, please contact your doctor to have your device returned for analysis and to request a replacement. Do not throw away the Remote Controller and/or Charger in the trash.

Things to Remember

- Always tell your doctor that you have an implanted Microstimulator before having any new medical or dental treatment.
- Contact your doctor if you have had a forceful impact to the head or neck region (head trauma).
- Avoid touching or putting excess pressure to the implanted Microstimulator. Excessive pressure placed on the Microstimulator may move it out of place or cause damage to the device.
- Carry your Patient Implant Identification Card with you at all times. In the event of an accident, the card will inform medical personnel that you have an implanted device.
- Call your surgeon immediately if you experience irritation or bleeding near your implant incision.
- Do not throw away your Remote Controller and/or Charger if it stops working.

10. TROUBLESHOOTING

If your Remote Controller and/or Charger are not working, please contact your doctor. The serial number is provided on the back of the Remote Controller. You may need to provide the serial number to your doctor. You may also have to return the Remote Controller and/or Charger for analysis and request a replacement.

If your Remote Controller does not work with your Microstimulator:

Check the battery indicator on your Remote Controller and, if needed, recharge the Remote Controller. Move away from any possible sources of electrical interference (for example, electric toothbrush charging stations, induction ranges, metal doors, etc.) and try again. Turn OFF and then turn ON your Remote Controller and try again. Press and hold the Power button for approximately 10 seconds until the screen displays the Pulsante® logo element and software version information (Figure 18). If none of the steps above works, please contact your doctor to request a replacement.

Figure 18: Remote Controller Screen with Logo Element and Software Version



If your Remote Controller will not turn ON:

Charge the Remote Controller and try again. If the Remote Controller does not recharge, please contact your doctor to request a replacement.

If you lose your Remote Controller:

Contact your doctor to obtain a replacement.

If fluid is spilled on the Remote Controller:

Dry the Remote Controller with a towel.

If the Remote Controller falls into water:

Contact your doctor to return your Remote Controller and order a replacement. Do Not use your Remote Controller to apply therapy after it falls into water or other liquids.

If the Remote Controller displays an Alert Indicator (Figure 19):

Your Remote Controller has detected a problem with mechanical functionality and is NOT delivering therapy. Turn off your Remote Controller, then turn it on again. If you have used the Remote Controller for two hours continuously (maximum time allowed), then the Remote Controller will display this Alert Indicator for 30 minutes to allow the Remote Controller to cool down. If the Alert Indicator remains on the screen for more than 30 minutes, contact your doctor for assistance.

Figure 19: Remote Controller Screen with Alert Indicator



If the Remote Controller begins to vibrate loudly:

Check the Display Screen for any alerts or notifications such as the Alert Indicator or the Depleted Battery symbol.

11. TECHNICAL DESCRIPTION AND SPECIFICATIONS

USA-Federal Communications Commission (FCC)

The following is communication regulation information on the Pulsante SPG microstimulator system comprises of Neurostimulator NS-100 and Remote Controller RC-300.

FCC ID of the system: 2APE8-RC300

Labeling Note: FCC ID information can be retrieved by pressing and holding the Remote Controller RC-300 power button for 10seconds.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This product does not contain any user serviceable components. Any unauthorized product changes or modifications will invalidate warranty and all applicable regulatory certifications and approvals, including authority to operate this device.

FCC Part 15 Digital Emissions Compliance We, Autonomic Technologies, Inc, declare under our sole responsibility that this product complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

WARNING: 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 and radiates radio frequency 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 the one the receiver is connected to.

Consult the dealer or an experienced radio/TV technician for help. The user may find the following booklet prepared by the Federal Communications Commission helpful: The Interference Handbook. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402. Stock No.004-000-00345-4.

Electromagnetic Compatibility

The use of cables other than those specified or sold by Autonomic Technologies may result in increased emissions or decreased electrical immunity of the system. The RF transmitter within the remote controller operates at 126 kHz +/- 3kHz, with Frequency Shift Keying (FSK), and the effective radiated power of less than 5mW. NOTE: The device remains safe under its typical electromagnetic interference environment. The Pulsante® SPG Microstimulator System complies with the international standard IEC 60601-1-2, Edition 4.0 2014-02 for Electromagnetic Compatibility (EMC). Use of this equipment should follow the Electromagnetic Compatibility (EMC) guidance below.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS			
The Pulsante® SPG Microstimulator System is intended for use in the electromagnetic environment specified below. The customer or user of the Pulsante® SPG Microstimulator System should assure that it is used in such an environment.			
EMMISSIONS/IMMUNITY TEST	TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Radiated and Conducted emissions - CISPR 11	Pending test results	Pending test results	Pending test results
Harmonic emissions - IEC 61000-3-2	Pending test results	Pending test results	Pending test results
Voltage fluctuations / Flicker emissions - IEC 61000-3-3	Pending test results	Pending test results	Pending test results
Electrostatic discharge (ESD) - IEC 61000-4-2	Pending test results	Pending test results	Pending test results
Electrical fast - Transient burst - IEC 61000-4-4	Pending test results	Pending test results	Pending test results
Surge - IEC 61000-4-5	Pending test results	Pending test results	Pending test results
Voltage dips, short interruptions, and voltage variations on power supply input lines - IEC 61000-4-11	Pending test results	Pending test results	Pending test results
Power frequency - 50/60 Hz magnetic field - IEC 61000-4-8	Pending test results	Pending test results	Pending test results
Conducted RF - IEC 61000-4-6	Pending test results	Pending test results	Pending test results
Radiated RF - IEC 61000-4-3	Pending test results	Pending test results	Pending test results

The Pulsante® SPG Microstimulator System is battery operated.

NOTE: The Pulsante® SPG Microstimulator System should not be used while stacked on or adjacent to other equipment. If stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used. Portable and mobile RF communications equipment can affect the System; the following separation distances are recommended.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PULSANTE® SPG MICROSTIMULATOR SYSTEM			
The Pulsante® SPG Microstimulator System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Pulsante® SPG Microstimulator System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulsante® SPG Microstimulator System as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (M)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	Pending test results	Pending test results	Pending test results
0.1	Pending test results	Pending test results	Pending test results
1	Pending test results	Pending test results	Pending test results
10	Pending test results	Pending test results	Pending test results
100	Pending test results	Pending test results	Pending test results
For transmitters rated at a maximum output power not listed above, the recommended separation distance is pending test results.			

Specifications for the Pulsante® Microstimulator:

STIMULATION PARAMETER	SPECIFICATION
Power Source	Resonant Inductive Coupling Powered, no finite life
Channels	Six (6) Channels
PHYSICAL CHARACTERISTICS	SPECIFICATION
Sizes	Short, Medium, Long, Extra-Long
Body	Pending test results
Weight	Pending test results
Volume	Pending test results
Storage Temperature	Pending test results

MATERIALS	SPECIFICATION
Microstimulator Body and Lead	Polyurethane-silicone co-polymer (Material Contacts Human Tissue)
Electrodes	Platinum (90%) / Iridium (10%) (Material Contacts Human Tissue)
Bone Fixation Plate	Titanium, Grade 2 (Material Contacts Human Tissue)

Specifications for the Pulsante® Remote Controller:

PHYSICAL CHARACTERISTICS	SPECIFICATION
Remote Controller Size	Pending test results
Weight	Pending test results
Case Material	PC-ABS
Connector	Micro USB Port
Storage/Operating/Transport Temperature Range / Humidity	Pending test results
ELECTRICAL CHARACTERISTICS	SPECIFICATION
Power	Built-in rechargeable lithium polymer battery
Battery Charge Life	Pending test results
Total Expected Life of Device	Pending test results
Operating Frequencies	Pending test results
Communication Method	Radio Frequency (RF)

Specifications for the Pulsante® Remote Controller Charger:

PHYSICAL CHARACTERISTICS	SPECIFICATION
Remote Controller Charger Size	Pending test results
Case Material	Pending test results
Connector	Micro USB
Length of Cord	1 meter
Storage/Operating/Transport Temperature Range / Humidity	Pending test results
ELECTRICAL CHARACTERISTICS	SPECIFICATION
Input Voltage	Pending test results
Output Voltage	Pending test results
Input Frequency	Pending test results
Output Current	Pending test results
Output Power	Pending test results
Switching Frequency	Pending test results

12. INFORMATION AND SUPPORT

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