

SPRINT™ extensa

Patient Instructions for Use



Kommentar [TLI]: This is revision F, right? I am confirming because the revision level isn't marked as a tracked change.

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Kommentar [MW2]: Need to update prior to final release

The SPRINT® PNS System is manufactured by:



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Information on patents can be found at:
www.sprtherapeutics.com/patents

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Table of Contents

Glossary	4
1 Introduction	5
1.1) About this Manual	5
1.2) Peripheral Nerve Stimulation (PNS) Therapy	5
1.3) Your SPRINT® PNS System.....	6
2 Important Safeguards	8
2.1) Purpose of the device (Indications for Use).....	8
2.2) When the device should not be used (Contraindications).....	8
2.3) Warnings, Precautions, & Risks	9
3 Battery & Charging your System	14
3.1) Checking the Rechargeable Battery Level	15
3.2) Charging the Battery	15
3.3) Removing / Changing the Battery.....	15 16
4 Using your SPRINT® PNS System	17
4.1) Your Therapy Type	17
4.2) Operating your Hand-Held Remote	17
4.3) Starting and Stopping Stimulation	18
4.4) 6hr Session Countdown Timer	20
4.5) Adjusting Stimulation.....	21
4.6) Selecting a Favorite	22
5 Connecting and Disconnecting the System	23
5.1) Connecting the System	23
5.2) Disconnecting the System.....	25
6 Cleaning & Care	26
6.1) Caring for the MicroLead Exit Sites	26
6.2) Changing the Waterproof Bandages and Connector Cradles	27
6.3) System Cleaning.....	29
6.4) Disposal	29
APPENDIX A Frequently Asked Questions	30
APPENDIX B Troubleshooting	31
APPENDIX C Specifications	34
APPENDIX D Symbols and Messages	40
APPENDIX E Contacting Customer Service	44
APPENDIX F MRI Safety Information	45
MRI Safety Card.....	46

Glossary

Caution – Information on how to prevent damage to or failure of your device.

Contraindication – When you should not use the SPRINT® PNS System.

Diathermy – A medical treatment applied to the outside of the body that delivers energy into the body.

Indication – The purpose of the SPRINT® PNS System.

Intensity – The strength of your stimulation.

Magnetic Resonance Imaging (MRI) – A medical test that lets doctors see inside your body.

Note (👁) – An important reminder for the use of your system.

Precaution – See Caution.

Provider – Your doctor that provides you with the SPRINT® PNS System.

Stimulation – The delivery of tiny electrical pulses to a nerve to cause therapeutic sensations.

Therapy – Treatment of a disease or condition. This system uses stimulation as its therapy.

Warning (⚠) – Describes an action or situation that could harm you.

1 Introduction

1.1) About this Manual

This manual describes your SPRINT® PNS System. It provides important use and safety information. Before you begin using your system, read this manual completely. Contact your provider if you have any questions or concerns. Keep your manual in a safe place, so you can refer to it in the future.

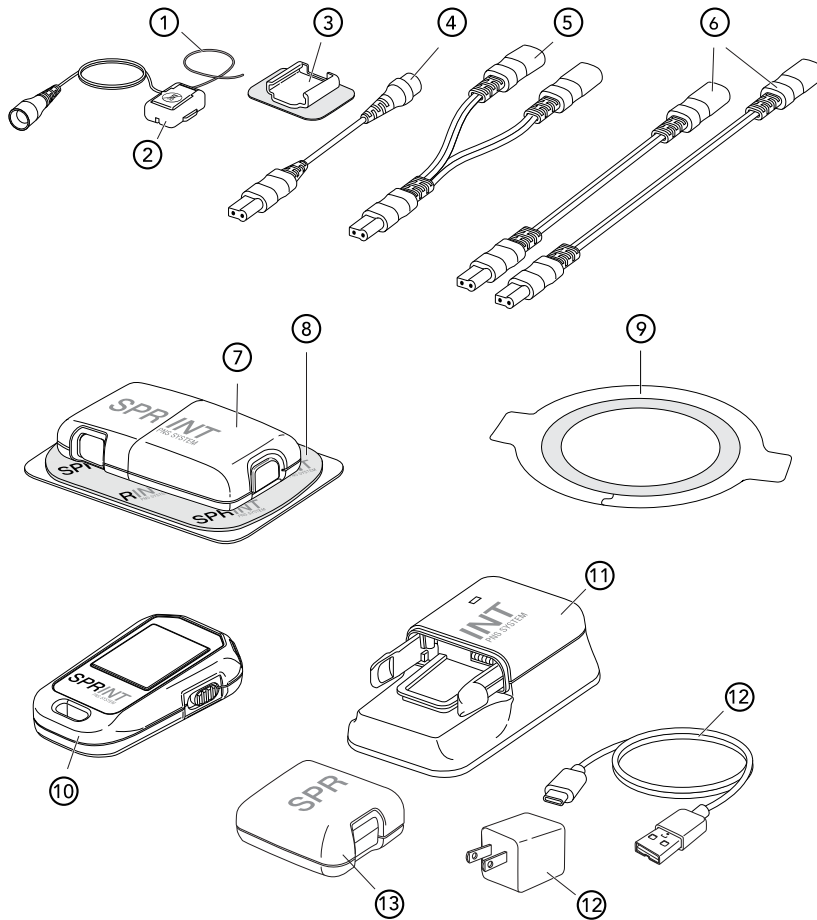
1.2) Peripheral Nerve Stimulation (PNS) Therapy

Your SPRINT System uses a small, wearable Pulse Generator (power source) connected to two MicroLeads. The leads are thread-like wires that deliver tiny electrical pulses, called stimulation. This stimulation targets specific nerves tied to the pain site. This helps to relieve your pain. The leads will be removed by your provider at the end of the therapy.

The System includes a Remote. The Remote lets you control your Pulse Generator and adjust the stimulation intensity.


NOTE: It is important that you follow the instructions given by your provider. They will show you how to set up your System and care for your skin, including the lead exit sites. Follow your provider's guidelines for best results.

1.3) Your SPRINT® PNS System



1. **MicroLead (2)**: A thin, thread-like wire. One end is inserted through your skin near a nerve. The other end remains outside of your body and attaches to the Pulse Generator using the MicroLead Connector and Cables.
2. **MicroLead Connector (2)**: Connects the MicroLead to the Magnetic Coupler.
3. **Mounting Cradle (2)**: Holds the MicroLead Connector in place under the Bandage.
4. **Magnetic Coupler (2)**: Connects the MicroLead Connector to the Pulse Generator. If your system is pulled or bumped, the magnets will separate to help keep the MicroLead in place.
5. **Dual Lead Adapter**: The adapter connects two MicroLead Connectors to one Pulse Generator.

6. **Short & Long Extensions (2):** Cables that provide extra length.
7. **Pulse Generator:** Delivers your peripheral nerve stimulation (PNS) therapy.
8. **Mounting Pad:** Connects the Pulse Generator to your skin. One side of the pad has a sticky gel to attach the pad to your skin. The non-sticky side of the pad has two snaps that connect to the Pulse Generator.
9. **Waterproof Bandage:** Keeps your MicroLead exit sites clean and dry.
10. **Hand-Held Remote:** Allows you to turn stimulation on and off and adjust intensity.
11. **Recharging Base:** Charges your Pulse Generator Rechargeable Batteries.
12. **Recharging Base Power Supply:** Power cord for your Recharging Base.
13. **Rechargeable Battery (2):** The Pulse Generator needs one Rechargeable Battery. Two batteries are provided so you can charge one while the other is in use.
14. **Patient Case (not pictured):** Includes Recharging Base, extra battery, Waterproof Bandages, Mounting Cradles, Mounting Pads.
15. **Patient Disposable Supplies Box (not pictured):** Includes additional Waterproof Bandages, Mounting Cradles and Mounting Pads.

 **NOTE:** Contact your provider if anything is missing or broken.

2 Important Safeguards

Carefully read the following information before using your SPRINT System. If you have any questions call your provider.

2.1) Purpose of the device (Indications for Use)

The SPRINT[®] Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 days in the back and/or extremities for:

- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

The SPRINT[®] PNS System is not intended to treat pain in the craniofacial region.

A randomized controlled trial failed to show that the SPRINT System was effective for post-stroke shoulder pain.

2.2) When the device should not be used (Contraindications)

Do not use the SPRINT[®] PNS System and consult your provider if:

- You have a deep brain stimulator (DBS) system.
- You have an Implanted active cardiac implant (e.g., pacemaker or defibrillator.)
- If you have any other implanted neuro-stimulator whose stimulus current pathway may overlap with that of the SPRINT System.
- You require Magnetic Resonance Imaging (MRI). The SPRINT[®] MicroLead and other SPRINT components must be removed from the body before you have an MRI.
- You have a tape or adhesive allergy.

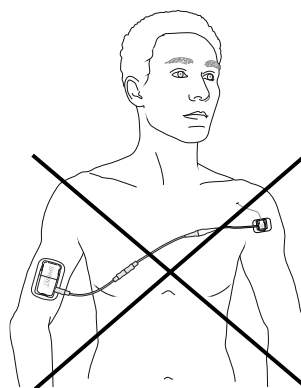
2.3) Warnings, Precautions, & Risks

Warning (⚠️) – Describes an action or situation that could harm you.

This section lists potential hazards associated with the SPRINT System that you must be aware of to avoid serious outcomes that may cause injury.

⚠️ SPRINT Mounting Pad Placement

- The SPRINT System is for use in the back and/or extremities.
- The SPRINT System is not intended to treat pain in the craniofacial region.
- Do not place the Mounting Pad on your head or the front of your throat — Stimulation in these areas may cause severe muscle spasms resulting in closure of your airway, difficulty breathing, an irregular heartbeat, or changes in your blood pressure.
- Do not place the Mounting Pad across the chest from the MicroLead — Electrical current across the chest may cause your heart to beat irregularly, which could be deadly.



⚠️ **Do not leave a child or pet unattended with cables** — Entanglement may result in strangulation.

⚠️ **Routinely inspect system for broken or missing parts** — Small parts may present a choking hazard to children and pets.


⚠️ **Routinely inspect your skin** — Inspect your skin for signs of infection, nerve or blood vessel damage. If you notice signs of redness, itching, swelling, or bruising near your MicroLead exit site, call your provider.

⚠️ **Do not connect any part of the SPRINT System which is touching or connected to your body to any power source (such as a wall outlet). This could cause serious injury or death.**


⚠️ **Operation of heavy machinery (driving, etc.)** — Do not use the System while driving, operating machinery, or during any activity in which involuntary (not under your own control) muscle tension may put you at risk of injury.

⚠️ **Pregnancy** — Safety for use during pregnancy has not been established.


⚠️ **Pediatric use** — Safety and usefulness have not been established for use in anyone 21 years of age or younger.


 **The SPRINT System is MR unsafe** — All MRI procedures anywhere on your body are not allowed while you are using the SPRINT System. Having an MRI procedure can cause tissue heating, injury, or unwanted stimulation. A medical professional should remove the MicroLead and all other System parts before an MRI is conducted. If a MicroLead breaks and a piece of the MicroLead remains under your skin, it is safe to receive an MRI under the conditions described in Appendix F.





 **A retained MicroLead fragment ONLY is MR conditional** — If a piece of the MicroLead remains under your skin after MicroLead removal, you can be scanned safely in an MR system under conditions described in Appendix F.



 **Diathermy** — You may not have any diathermy anywhere on your body while MicroLeads are in place. Diathermy is a medical treatment applied to the outside of the body that delivers heat into the body. Heat from diathermy can be transferred to your leads and can cause tissue damage and possibly severe injury. Diathermy can also damage your Pulse Generator and Mounting Pad. Serious burns of the skin and tissue under the Mounting Pad may occur.

 **Do not take apart or modify any part of the SPRINT System** — Taking apart or modifying a piece of the System may cause injury to you or damage to your System.

 **Do not use any piece of the SPRINT System with a component that is not part of the System** — Doing so may cause injury to you or damage to your System.

 **Disinfecting the SPRINT System** — Disinfect your System before and after entering a hospital, clinic, or medical office. Follow your healthcare provider's guidance. Keep your system clean. Dispose of any used Mounting Pads when entering or leaving a hospital, clinic, or medical office. See section 6 — "Cleaning and Care" for more information.

Precaution - Information on how to prevent damage to or failure of your device.

This section lists instructions you should follow to avoid situations that may cause discomfort or damage your System.

Stimulation sensation while walking — Use caution while walking if receiving stimulation in your legs until you feel comfortable with how your therapy feels.

Mounting Pad placement — Pads should only be placed on clean healthy skin. Placement on unhealthy skin (for example, injured skin, or rashes) may further irritate the area and cause discomfort. It is okay to apply the Pad to a birthmark or hair bearing areas. If you experience sensitivity or the pad does not stick well, move the Pad to another spot.

MicroLead Connector and Mounting Cradle Placement — To reduce the risk of infection, do not place the Connector or the Cradle directly on top of the Lead exit site.

Painful stimulation — If stimulation is painful, turn stimulation intensity down. If stimulation is still painful, turn stimulation OFF. Tell your provider that the stimulation is painful. If you are unable to turn stimulation off, remove the Pulse Generator from the Pad or unplug the cables from the Pulse Generator.

Broken or disconnected MicroLead or cable — Avoid pulling on the MicroLead or anything connected to it. This may cause the lead to be pulled out. If the lead or any cable breaks, call your provider. If a cable becomes disconnected, stop stimulation and reconnect the parts. A broken or disconnected lead or cable may deliver safe, but uncomfortable stimulation for a few seconds.

Other medical conditions — Follow your provider's instructions if you have suspected or diagnosed heart disease or epilepsy. Also, if you tend to bleed internally (or you take medications that make your blood thinner, or if you are receiving stimulation near a surgical site, notify your provider.

Electronic medical equipment — The Pulse Generator may interfere with patient monitoring equipment or other medical tools. Before any medical tests or procedures, ask your provider if the procedure might harm your SPRINT System. Always turn off and disconnect your System before any tests or procedures begin.

Theft and metal detectors — Theft and metal detectors found in places like libraries and stores may temporarily interfere with your SPRINT System. They will not damage your System. Walk through and do not stay near the theft or metal detector longer than needed.

Portable and mobile Radio Frequency (RF) communications — Portable and mobile Radio Frequency (RF) equipment can interfere with the System. Do not use this equipment while using the SPRINT System.

Electromagnetic Interference (EMI) — The System is not likely to cause any interference to other equipment other than possible Bluetooth interactions.

- **System interference with nearby devices:** The SPRINT System may interfere with nearby RF devices (radios, TVs, cell phones). The System uses Bluetooth wireless communication in the

Pulse Generator and Remote. Too many Bluetooth devices in use at one time can disrupt one or more of the devices.

- If moving away from another device solves the problem, it is likely that the System is interfering with the other device. Move so that your SPRINT System does not interfere with the other device.
- **Nearby device interference with the System:** The SPRINT System may be disrupted by other RF devices (radios, TVs, cell phones).
 - Disruptions are most likely to cause an inability to use the Remote to control the Pulse Generator, or temporary changes to stimulation. Stimulation turning OFF is also a possibility.
 - Portable RF equipment (especially cell phones) should not be used closer than 30cm (12 inches) to the Pulse Generator or Remote to avoid disruption of the SPRINT System. If disruption occurs, there is no risk of injury.
 - Stimulation can always be turned OFF by pressing the button on the Pulse Generator, removing the Pulse Generator from the Pad, or by unplugging the cables.
- For more details on EMI, contact Customer Service (see *Appendix E: Contacting Customer Service*).

Note (FCC Compliance): 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.

- Changes or modifications made to the system or system components not expressly approved by SPR Therapeutics will void the authority to operate the system.
- The FCC ID of the Hand-held Remote (2AO2X-9620) is displayed on the initial splash screen after being unlocked. The FCC ID of the Pulse Generator (2AO2X-9620) is located on the label on the back the device

Kommentar [MW3]: Required statement per 47 CFR 15.21

Kommentar [MW4]: Required per 47 CFR 2.935

Handle the SPRINT System with care. Be careful when handling. Dropping or crushing can damage your System.

MicroLead movement — Do not adjust the leads. Pulling on the lead will cause it to move from its location. A change in how your therapy feels may mean that the lead has moved. If you therapy becomes painful, stop using your System and call your provider.

The SPRINT System is not water proof — Do not submerge the System in water, alcohol, other fluids, or dust. Exposure to fluids (like water) or dust could damage the System. This may cause it to stop working or produce discomfort. Note: adding a drop of water to the sticky side of the Pad before use to improve stickiness is okay.

Battery care – The batteries may become unsafe if taken apart. They may short when battery connections contact metal or when exposed to high heat or fire. The materials in the battery can discolor skin and are not safe to ingest. Do not leave the System in a closed vehicle in hot temperatures.

Long term effects — The long-term effects of stimulation are unknown.

There are no user serviceable parts in the SPRINT System.

Risk – a possible side effect of the therapy.

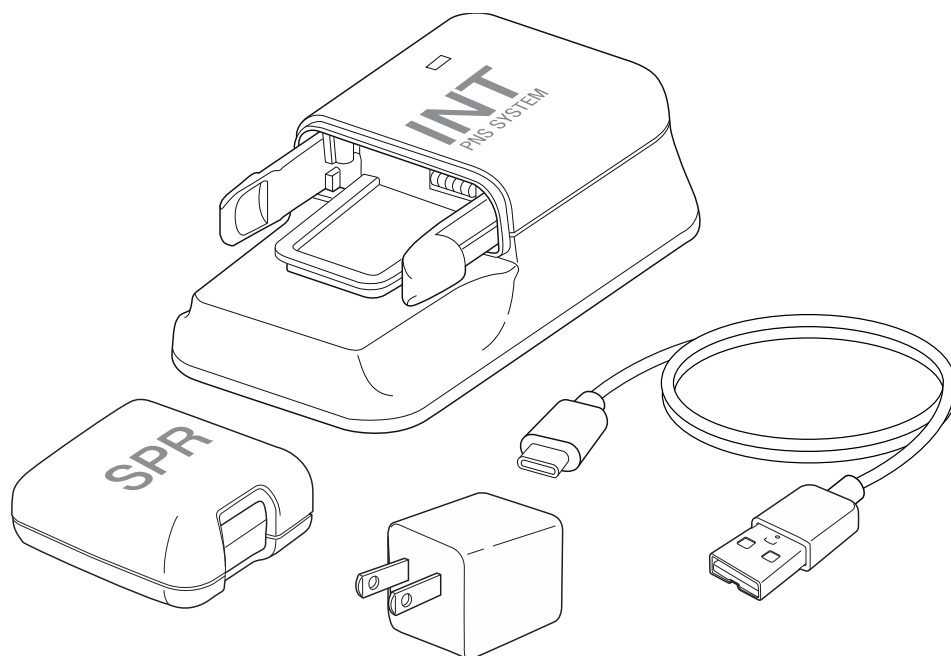
The following risks are associated with use of the SPRINT System. See Warnings and Precautions sections for additional risks.

- Skin irritation, infection, or mild tissue inflammation may occur at the Lead exit site.
- The Lead may break beneath your skin either during your therapy or during removal. An infection may occur if a piece of the lead remains in your body. If signs of infection occur, call your provider.
- Your skin could become irritated while using the Mounting Pad. Check your skin for irritation after removing the Pad from your skin. Some redness is normal. To minimize irritation, refer to *Section 6: Cleaning & Care*.
- Stimulation may be uncomfortable at high levels. If uncomfortable or painful, decrease the intensity or turn off stimulation and call your provider.

If you have any side effects or problems with the device, stop use and call your provider.

3 Battery & Charging your System

Your System has two Rechargeable Batteries, a Recharging Base, and Recharging Base Power Supply. How often you need to charge your battery depends on your stimulation intensity and how often you use the system.

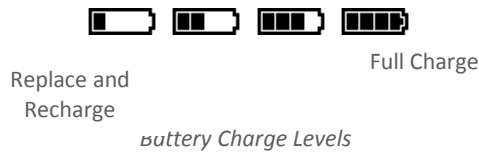


NOTE: When you first bring your system home, put the spare battery in the Recharging Base to charge. Always have one battery charging so that you never miss your daily therapy.

3.1) Checking the Rechargeable Battery Level

To check your battery charge level, unlock your Remote by moving the Lock/Unlock Switch to the Up/Unlocked position. See Section 4.2: *Operating your Hand-Held Remote*.

The home screen will display the battery charge level icon .

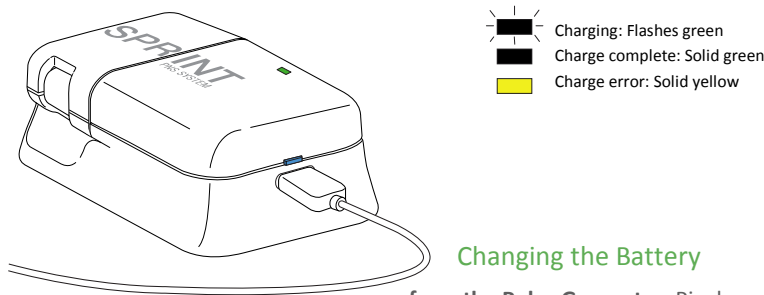


When your battery is fully charged, the icon will show four bars. Recharge your battery when the icon shows one bar. Your remote may display a message stating "Recharge Battery" when battery charge is low. The Pulse Generator will also emit tones (3 short beeps) and will flash yellow when your battery is low.

3.2) Charging the Battery

To recharge a used battery:

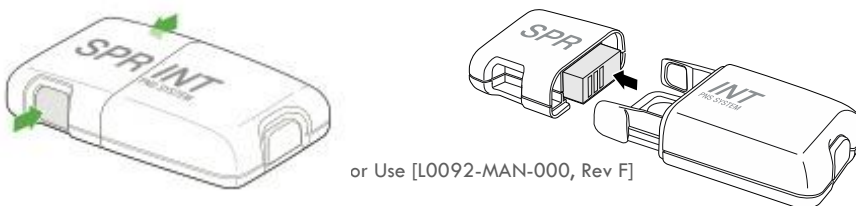
1. Plug the Recharging Base Power Supply into a wall outlet.
2. Slide the used battery into the Recharging Base until the battery clicks into place. Connect the Power Supply to the Recharging Base.
3. When the Base is plugged in, the power LED located above the cable will turn blue.
4. When the battery is charging, the battery charge level LED on the top of the Base will flash green.
5. Once the battery is fully charged, the battery charge level LED will turn solid green. If LED is yellow, refer to troubleshooting. (Appendix B)



3.3) Removing /

To remove a battery

from the Pulse Generator: Pinch the tabs on both sides of the Pulse Generator until the battery releases. Slide the battery out.



To insert a battery into the Pulse Generator: Slide the battery into the Pulse Generator until it clicks into place. Once inserted, you will hear a short beep and a light to show the charge level of the battery (as shown below).

Light Displayed	Associated Battery Charge Level
5 second Green light	Partial to Full charge
5 second Yellow light	Low charge
Flashing Yellow light	Critically Low charge; Replace and recharge the Rechargeable Battery

4 Using your SPRINT[®] PNS System

4.1) Your Therapy Type

Your provider will prescribe either 24hr Continuous Therapy or 6hr Session Therapy.

24hr Continuous Therapy

If you have 24hr Therapy, you should have stimulation on all day and night. You should only stop and disconnect your system when you need to shower, change bandages or when a warning or precaution applies (for example, do not have therapy on while operating heavy machinery; See *Section 2 Important Safeguards* for more information).

6hr Session Therapy

If you have 6hr Session Therapy, you should have stimulation on for 6hrs each day. Your Remote will keep track of how long stimulation has been on using a 6hr timer (see *Section 4.4: 6hr Session Countdown Timer*).

4.2) Operating your Hand-Held Remote

To unlock your Remote:

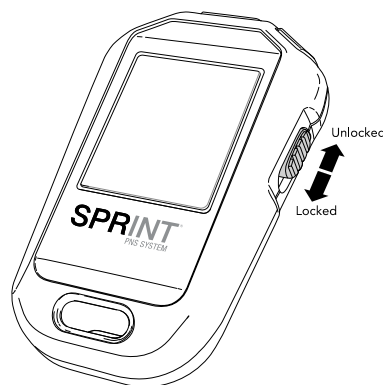
Move the Lock/Unlock Switch to the up position.

To lock your Remote:

Move the Lock/Unlock Switch to the down position.

To wake up your Remote:

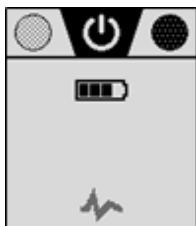
Your Remote will go to sleep after a period of inactivity. To wake up the Remote, press any button or move the Lock/Unlock Switch to the Up/Unlocked position.





The startup screen will show for a few seconds while the Remote connects to the Pulse Generator.

4.3) Starting and Stopping Stimulation


Using Your Hand-Held Remote



To turn stimulation on with your Remote, press the  button (the button above the  symbol).




Turning stimulation on will turn both leads on.

The  icon will appear and begin flashing, to show that stimulation is on. The Pulse Generator light will briefly flash green when stimulation is turned on.

The clock on the screen (if shown) is the therapy session time left (see Section 4.4 below) .



To turn stimulation off with your Remote, press the  button.

OFF will appear on the home screen, to show that stimulation is turned off.

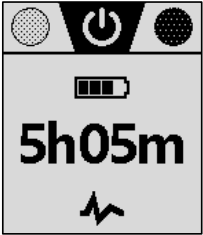



Using your Pulse Generator

You can also start and stop stimulation from your Pulse Generator by pressing the side button. The light under the button will turn green when turned on or off.

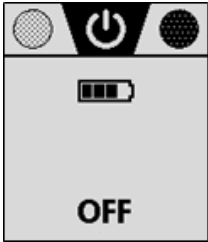


4.4) 6hr Session Countdown Timer

If you have been prescribed 6hr Session Therapy, your Remote home screen will show a 6hr countdown timer once stimulation has been turned on. Countdown timer is only displayed for 6hr sessions. You will not see a timer if you have continuous therapy (24hr).

	<p>Once stimulation has been turned on, the  icon will appear and begin flashing. And the countdown timer will begin counting down from 6h 00m</p>
	<p>If you stop (pause) stimulation during your 6hr session, the home screen will display the amount of time you have left to complete.</p>
	<p>After being OFF for more than 2hrs, the Remote will ask if you would like to continue the current session. Press the "Con" button to continue the current session or press the "New" button to start a new session.</p> <p>* If OFF for more than 12hrs, the countdown timer will return to 6h 00m.</p>

4.5) Adjusting Stimulation



To adjust stimulation on the first MicroLead (which is connected to the light Connector) press the light ● button from the home screen.

OR

To adjust stimulation on the second MicroLead (which is connected to the dark Connector) press the dark ● button from the home screen.

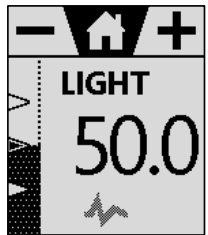


When stimulation is OFF, as shown by the OFF indicator:

To decrease stimulation intensity, press the – button.

(Holding the – button will cause the intensity to decrease as long as you hold the button.)

You cannot increase stimulation intensity when stimulation is OFF.

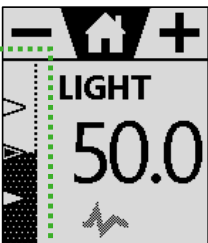


When stimulation is ON, indicated by the ⚡ icon:

To decrease stimulation press the – button.

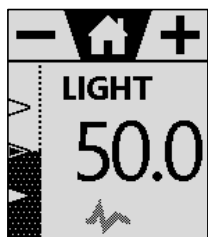
To increase stimulation press the + button.


(Holding the + button will cause the intensity to increase as long as you hold the button.)



After increasing or decreasing stimulation, the screen will change to show the new intensity value.

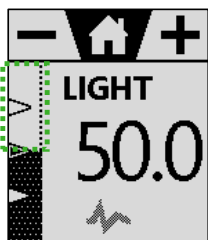
The dark bar on the left side of the screen shows where the intensity value falls within the minimum and maximum set by your provider.



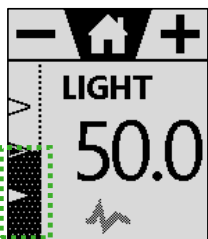
To turn stimulation on or off, or to adjust the second MicroLead, press the  button to return to the home screen.

4.6) Selecting a 'Favorite'

Some providers may choose to pre-set stimulation intensity settings (favorites). If set by the provider, the favorites allow you to move directly to these preset values and you will see small triangles on the left hand side of the screen.



To move directly to the next highest preset value, press and hold the **+** button and then press the **-** button at the same time.



To move directly to the next lowest preset value, press and hold the **-** button and then press the **+** button at the same time.

5 Connecting and Disconnecting the System

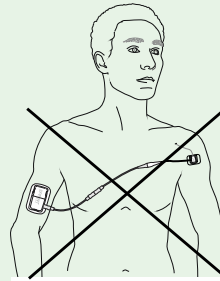
5.1) Connecting the System

1. Prepare the Mounting Pad Placement Site
 - Clean the areas, clipping (not shaving) hair as needed
 - Skin oils may be removed by wiping skin with rubbing alcohol

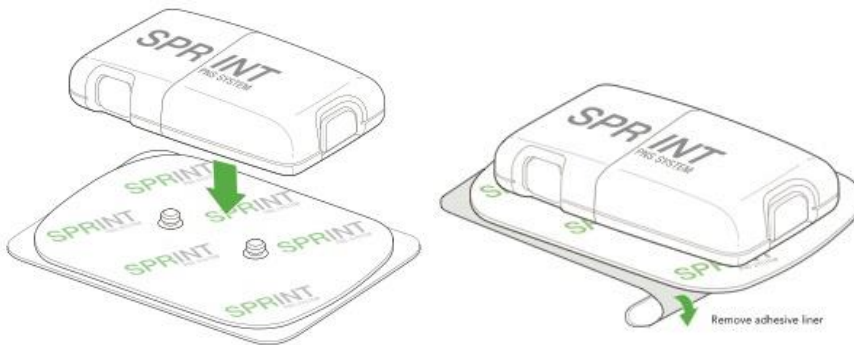
! **WARNING:** Never place the Mounting Pad or Pulse Generator across the chest from the MicroLead — Electrical current across the chest may cause your heart to beat irregularly, which could be deadly.

! **WARNING:** Do not place the Mounting Pad on your head or the front of your throat — Stimulation in these areas may cause severe muscle spasms resulting in closure of your airway, difficulty breathing, an irregular heartbeat, or changes in your blood pressure

! **PRECAUTION:** Pads should only be placed on clean healthy skin. Placement on unhealthy skin (i.e. injured skin, or rashes) may further irritate the area and cause discomfort. It is okay to apply the Pad to a birthmark or hair bearing areas. If you experience sensitivity or poor adhesion, move the Pad to another spot.



2. Snap the Pulse Generator onto the Pad.
3. Remove the Pad liner by lifting up from one corner.



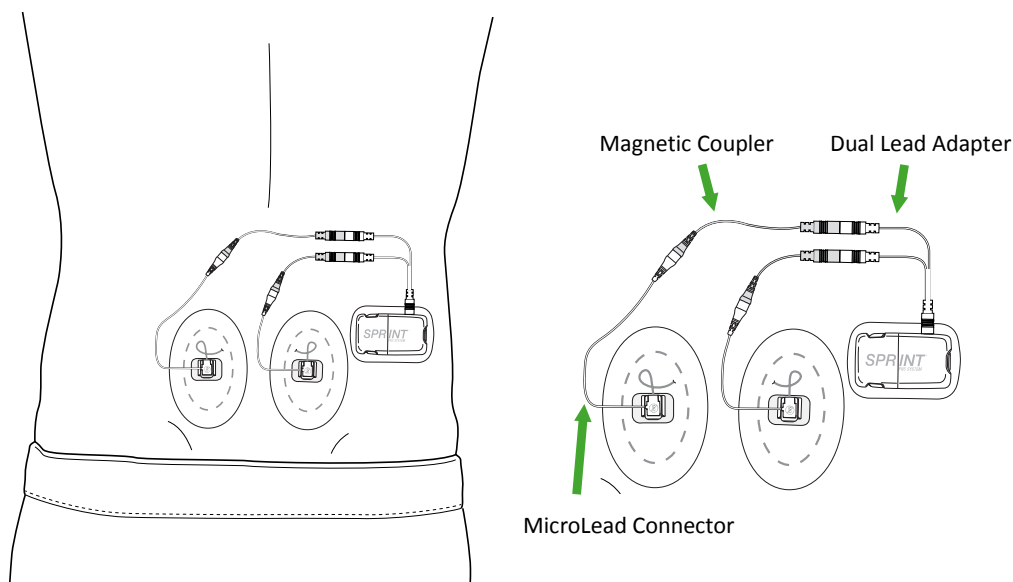
4. Place the Pad with the Pulse Generator in the location advised by your provider.

Chapter 5: Connecting & Disconnecting the System

- Be sure the Pad location does not put tension on your MicroLead Connectors.
- Make sure the entire Pad surface is stuck to your skin.

NOTE: If the Pad does not stick well, add a drop of tap water to the sticky (gel) side prior to use. Replace with a new pad when needed.

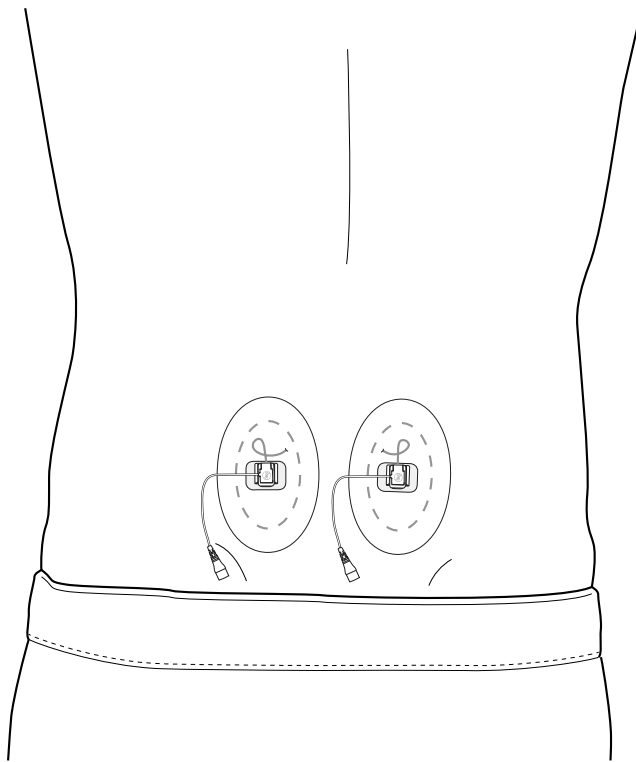
5. Connect the Pulse Generator to the Dual Lead Adapter.
6. Connect both Magnetic Couplers to the Dual Lead Adapter.
7. Connect the light Coupler to the light MicroLead Connector, using a light short or long extension if needed.
8. Connect the dark Coupler to the dark MicroLead Connector, using a dark short or long extension if needed.



5.2) Disconnecting the System

To disconnect your system before showering or when therapy is off:

1. Turn stimulation OFF using the Remote or Pulse Generator. The home screen will display OFF showing that your Pulse Generator is no longer delivering stimulation. (see *Section 4.3: Starting and Stopping Stimulation*)
2. Disconnect the MicroLead Connectors from the Magnetic Couplers.
3. Unsnap the Pulse Generator from the Mounting Pad.
4. Remove the Mounting Pad by slowly peeling it off your skin. Return the Pad to its liner if it will be reused.



6 Cleaning & Care

Your provider will show you how to care for your skin and lead exit sites (where the MicroLead goes through your skin). They will also discuss how and when to change the Waterproof Bandages and Mounting Cradles.

6.1) Caring for the MicroLead Exit Sites

It is very important that you keep your exit sites clean and dry at all times.

To keep your skin healthy and minimize risk for infection, follow these instructions:

- Keep the exit sites clean and dry.
- Use Bandages to cover the exit sites and MicroLead Connectors.
- Never soak the exit sites in water. It is okay to shower with Bandages in place over the exit sites.
- Before placing the Pads, Cradles, or Bandages, wash the area of skin with soap and water. Allow to dry.
- Skin oils may be removed by wiping skin with rubbing alcohol.
- Change your Bandages as needed. Especially if it becomes loose or if the inside of the bandage gets wet.
- Check your skin each time the Bandages are changed for signs of infection.



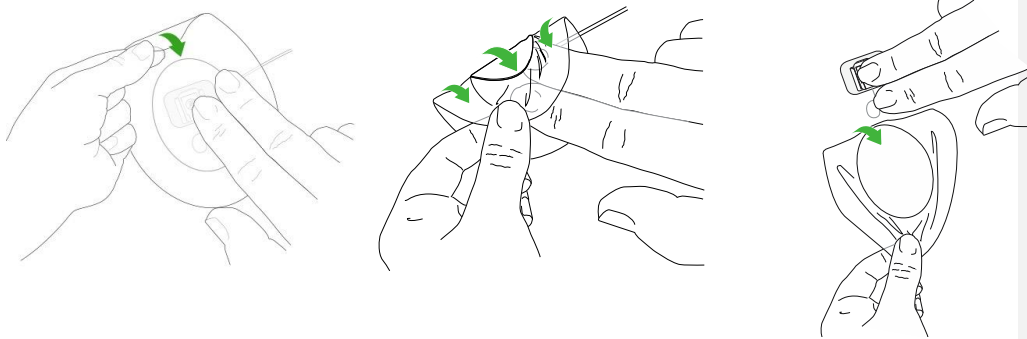
WARNING: Watch the exit sites for signs of infection. These include redness, swelling, drainage, bleeding or a bad smell. Immediately tell your provider if any of these are present.

6.2) Changing the Waterproof Bandages and Mounting Cradles

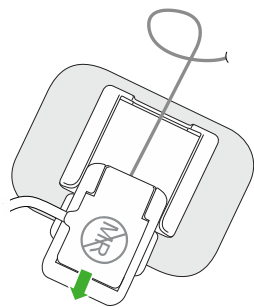
If the Waterproof Bandages or Mounting Cradles are soiled, damp, or starting to peel, they must be replaced.

Follow these instructions to replace:

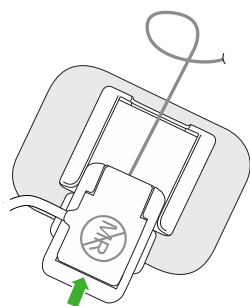
1. Wash your hands.
2. Hold the Connector stable while peeling off the old Bandage.



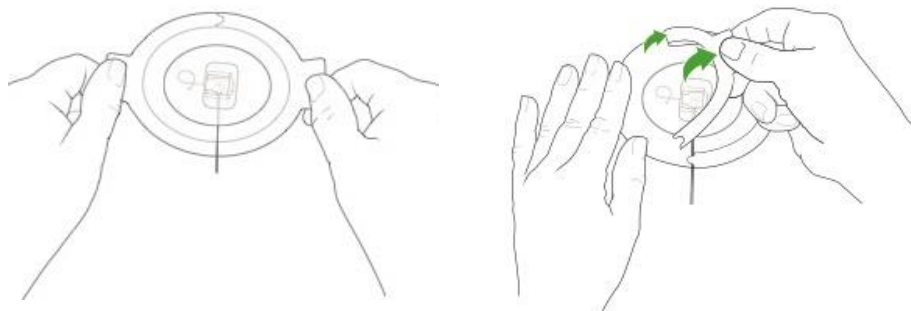
3. Wash your hands again.
4. Clean the exit site with soap and water. Allow to dry.
5. Check if the Cradles need to be replaced.
 - If so, slide the Connector out of the Cradle. Avoid pulling on the MicroLead.



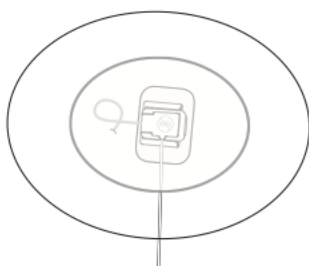
- Peel off the Cradle and replace it with a new one.
- Slide the Connector (with the MR symbol facing up) into the Cradle.



6. Place the center of the new Bandage over the MicroLead exit site. Make sure that no portion of the bandage adhesive touches the MicroLead exit site or Connector.
7. Press the sticky edges of the bandage firmly onto your skin so no water can enter the MicroLead exit



site. The Connector cable will pass underneath the edge of the bandage. (see *Section 5.1: Connecting the System*)



! WARNING: Do not let the adhesive portion of the bandage touch the MicroLead exit site or the MicroLead Connector. This could result in the MicroLead being pulled out.

! WARNING: To reduce the risk of infection, do not place the MicroLead Connector or the Mounting Cradle directly on top of the MicroLead exit site.

6.3) System Cleaning

Clean your System as needed. Also clean it before and after entering a hospital, clinic, or medical office.

- Use a soft cloth. Dampen the cloth with soapy water to wipe down the Pulse Generator or cables.
- Do not submerge the Pulse Generator or allow the cables to become wet.
- If the Pulse Generator or cables become wet, dry them off before use.
- Your provider may give you special instructions on how to clean your system.
- Dispose of any used Mounting Pads when entering or leaving a hospital, clinic, or medical office.

6.4) Disposal

Disposal of all System parts must comply with national, state, and local laws governing the disposal of such items.

Rechargeable Batteries and the Remote must never be disposed of in a fire because they contain batteries.

APPENDIX A

Frequently Asked Questions

If you have more questions, call your provider.

Can I shower?

Disconnect the System as described in *Section 5.2 Disconnecting the System*. Continue to use the Waterproof Bandages to keep the exit site areas, including the MicroLead Connectors, dry during showering.

Can I take a bath? Can I swim?

Do not take a bath or swim. Do not soak the exit sites in water.

Can I walk with stimulation on?

Use caution while walking if receiving stimulation in your legs until you feel comfortable with how your therapy feels.

Can I drive while using the System?

Do not use the System while driving, operating machinery, or during any activity in which involuntary (not under your own control) muscle tension may put you at risk of injury.

Instructions for air travel with the System?


The System includes small lithium batteries. Follow all Federal Aviation Administration (FAA) regulations or other international regulations for the storage and packing of lithium batteries in carry-on bags when flying with your System.

SPRINT® PNS system may set off airport security systems. To avoid major delays or problems, bring your Instructions for Use which explains the purpose and nature of the system.

How much (how many hours per day) should I use stimulation?

Your provider will prescribe the amount of therapy you should receive every day.

How do I know stimulation is working?

When stimulation is on, the  icon will be pulsing on the home screen of the Remote.

Do I have to remember to turn stimulation off?

No. If a session is less than 24hr, stimulation will stop automatically at the end of the session. For 24hr therapy, stimulation is left on except for showering or bandage changes.

What do I do if I lose or run out of a part?

Call your provider to request replacement parts.

Can I take the MicroLeads out myself?

No, the MicroLeads must be removed by your provider.

How often do I change the Rechargeable Battery?

It will depend on the intensity of the stimulation you receive. Check your battery charge icon and replace and recharge the batteries as needed.


How do I increase or decrease stimulation intensity?

See *Section 4.5 Adjusting Stimulation*.

APPENDIX B

Troubleshooting

If you have more questions, call your provider.

Problem	Possible Causes	Actions to be Taken
Mounting Pad is not sticking to skin	Skin is oily	Clean skin with mild soap and water and allow skin to dry OR wipe skin with an alcohol pad and allow to dry
	Pad has lost its stickiness	Apply a drop of tap water to the sticky side OR use a new Pad
Battery symbol is blinking	Rechargeable Battery is low	Replace and recharge the Battery
Screen shows "Recharge Battery"	Rechargeable Battery is low	Replace and recharge the Battery
Screen shows "Replace Remote Battery" or has a fixed screen and does not respond to button presses	Remote battery is low	Open the Remote battery compartment using a small screwdriver; Replace standard CR2032 battery. Warning: the coin cell battery is a swallow hazard for infants and small children; dispose of promptly. Disposal must comply with national, state and local laws governing the disposal of such items.
Session time is not decreasing	Therapy has been paused or was not yet turned on	Turn therapy on by pressing the  button
Screen shows "Lead Connect Error"	Magnetic Couplers or Short or Long Extension not fully connected to Pulse Generator	Check connection between cable and Pulse Generator
	Magnetic Couplers not fully connected to Short or Long Extension	Check connection between cables
	Magnetic Couplers not fully connected to MicroLead Connector	Check connection between Magnetic Breakaway and MicroLead Connector

Appendix B: Troubleshooting

Problem	Possible Causes	Actions to be Taken
	Mounting Pad not well adhered to skin	Ensure Mounting Pad is secured to skin OR see troubleshooting section “Mounting Pad is not sticking to skin”
	Issue with the MicroLead Connector or MicroLead	Call your provider
Stimulation will not turn on	Rechargeable battery is too low	Replace and recharge the Battery
	Lead Connect Error	See troubleshooting section “Screen shows Lead Connect Error”
Buttons are not working	Lock Switch is on	Move switch to unlocked (up) position
Stimulation sensation changes Note that minor changes in sensation with posture are common. Increase or decrease the stimulus intensity if desired.	Mounting Pad in different place than usual	Reposition Mounting Pad
	Mounting Pad not sticking to skin well	See troubleshooting section “Mounting Pad is not sticking to skin”
	MicroLead has moved	Call your provider
Pulse Generator not working correctly	Pulse Generator issue	If the Hand-Held Remote displays “Internal Error”, “Wireless Error”, “Lead Connect Error”, “Recharge Battery”, or “Replace Remote Battery” see the corresponding troubleshooting section Try removing and replacing the Rechargeable Battery; turn stimulation back on and resume use If problems persist, call your provider
Screen shows “Internal Error”	Pulse Generator issue	Try removing and replacing the Rechargeable Battery; Turn stimulation back on and resume use If problems persist, call your provider
Screen shows “Wireless Error”	Hand-Held Remote out of range	Ensure Hand-Held Remote is within arm’s length of the Pulse Generator; Move lock switch down and up to retry connection

Appendix B: Troubleshooting

Problem	Possible Causes	Actions to be Taken
	Bluetooth wireless connection issue	Try removing and replacing the Rechargeable Battery; turn stimulation back on and resume use
Stimulation is painful	Pulse Generator issue OR MicroLead has moved	Turn stimulation off. If stimulation will not turn off, remove the Rechargeable Battery from the Pulse Generator. Call your provider
Stimulation turns off on its own	Rechargeable Battery is too low	Replace and recharge the Rechargeable Battery
	An error has occurred	Turn stimulation back on and continue use. If the screen displays an error message, follow directions in the corresponding troubleshooting section
Stimulation turns off on its own and cannot be restarted.	The end of the maximum treatment duration (60 days) has been reached.	Call your provider

APPENDIX C

Specifications

All the components of the SPRINT System are suitable for storage and transportation between at least -20°C (-4°F) and 55°C (131°F). This includes the products in their shipping carton as well as the product as stored by the clinician or patient between uses.

All the components of the SPRINT System are suitable for use under the following operating conditions:

- a temperature range of 5°C (41°F) to 40°C (104°F);
- a relative humidity range of 15 % to 90 %, non-condensing, with not more than 50 hPa of water vapor pressure; and
- an atmospheric pressure range of 700 hPa to 1 060 hPa.

SPRINT Waterproof Bandage (REF A0009)

Parameter	Specification
Bandage	3M Tegaderm™ + Pad REF 3587

SPRINT MicroLead (REF 4536)

Parameter	Specification
Stimulating electrode	Length: 1.5 cm Surface area: 10mm ² (minimum)
Maximum resistance	150 ohms
Sterility	Provided sterile by Ethylene Oxide and non-pyrogenic

SPRINT Pulse Generator (REF 9610, with Rechargeable Battery: REF 9612)

Parameter	Specification
Dimensions	Approximately 6.2cm X 3.7cm X 1.4cm
Mass	Approximately 30g
Controls & Indicators	Control and multicolor Visual Indicator is a Momentary Pushbutton on the side of the Pulse Generator's housing; The Pulse Generator also generates audio attention tones
Wireless Communications	Bluetooth (Low Energy)
Output Control	Amplitude range: 0.2mA to 30mA (+/-5% for all Amplitudes above 5.0mA; below 5.0mA, accuracy of total per pulse charge is specified) Frequency range: 12 – 100 Hz (+/- 0.5% averaged over 10 pulses; +/- 10% pulse-to-pulse) Pulse duration range: 10µs - 200µs (+/- 4µs; below 2mA, the minimum Pulse Duration is 20µs)

Appendix C: Specifications

Parameter	Specification
	Duty cycle range: 50% - 100%
Stimulus Waveform	Asymmetric biphasic, no net DC
Maximum Charge Per Pulse	4 μC (For stimulus pulses with 50nC or less charge, the total per pulse charge delivered accurate to +/- 15%)
Maximum Charge Density at Stimulating Electrode	0.4 $\mu\text{C}/\text{mm}^2$ (when in use with the SPRINT MicroLead)
Maximum Current Density at Return Electrode (Pad)	0.06mA _{RMS} / cm ² (1.4mA _{RMS} / 25cm ²)
Range of Load Impedance	200 Ω to 1,300 Ω
Maximum DC Current Component of Output	<1 μA
Rechargeable Battery	240mA-hr Lithium Ion Polymer cell with protective circuitry in protective housings
Time to recharge a fully exhausted Battery	Approximately 4 hours
Typical Battery Operating Time	Dependent on the stimulus parameters in use; most patients will be able to use the Pulse Generator for 12 to 24 hours on a fully charged Battery; Baseline Operating Life: 24 hours of continuous stimulation with 1-channel stimulating at 100Hz, 20mA, 80 μs , 100% duty cycle into a 1,500 Ω patient circuit resistance.
IEC 60601-1 classification and designations	<ul style="list-style-type: none"> • Type BF equipment • Internally powered • NOT suitable for use with flammable anesthetic agents • Suitable for use in the Home Healthcare Environment and the Professional Healthcare Environment
Service Life	60 calendar days after the Pulse Generator is first programmed

SPRINT Recharging Base (REF 9615)

Parameter	Specification
Size	Approximately 7.2cm X 4.2cm X 2.6cm
Mass	Approximately 60g
Controls & Indicators	No controls; two visual indicators; Blue light (next to the receptacle for the USB Power Adapter plug) indicates DC power is being supplied to the unit; The indicator on the top of the housing indicates if the

Appendix C: Specifications

Parameter	Specification
	Rechargeable Battery is charging (flashing Green), is fully charged (continuous Green), or is not charging (Yellow).
Charging Protections	Circuitry prevents recharging unless Rechargeable Battery cell is within specifications and the cell voltage is suitable for charging
Charging Current	115mA.

SPRINT Recharging Base Power Supply (REF 9616)

Parameter	Specification
Size	Approximately 3.9cm X 3.3cm X 2.4cm
Description	Commercially available USB Power Adapter (with integral plug cap for US market)
Safety Certifications	UL (60950-1); FCC Part 15 class B;
Output	5.00V (+/- 0.24V) at up to 1.0A DC (0.15A is required)
Mains Power	90VAC – 264VAC; 50Hz or 60Hz

SPRINT Mounting Pad (REF 9618)

Parameter	Specification
Size	Approximately 7.9cm X 5.4cm X 3.9cm
Skin Contacting Material	Hydrogel

SPRINT Hand-Held Remote (REF 9620)

Parameter	Specification
Size	Approximately 6.5cm X 4cm X 1.7cm
Mass	Approximately 25g
Wireless Communications	Bluetooth (Low Energy)
Internal Battery	Lithium Coin Cell (CR2032) {user replaceable with the use of a screwdriver}
Service Life	60 days of typical daily use

SPRINT MicroLead Connectors (REF 9650 & 9655)

Parameter	Specification
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Appendix C: Specifications

Parameter	Specification
Colors	Light Gray (REF 9650) Dark Gray (REF 9655)
Connector	Proximal end: touchproof magnetic connector Distal end: insulation displacement connector

SPRINT Mounting Cradle (REF 9661)

Parameter	Specification
Skin Contacting Material	Adhesive Bandage

SPRINT Dual Lead Adapter (REF 9670)

Parameter	Specification
Connector	Proximal end: two touchproof keyhole connectors Distal end: touchproof keyhole connector

SPRINT Short Extensions (REF 9680 & 9681)

Parameter	Specification
Colors	Light Gray (REF 9680) Dark Gray (REF 9681)
Connector	Proximal end: touchproof keyhole connector Distal end: touchproof keyhole connector

SPRINT Long Extensions (REF 9685 & 9686)

Parameter	Specification
Colors	Light Gray (REF 9680) Dark Gray (REF 9681)
Connector	Proximal end: touchproof keyhole connector Distal end: touchproof keyhole connector

SPRINT Magnetic Couplers (REF 9690 & 9695)

Parameter	Specification
Colors	Light Gray (REF 9690) Dark Gray (REF 9695)

Appendix C: Specifications












Parameter	Specification
Connector	Proximal end: touchproof magnetic connector Distal end: touchproof keyhole connector

APPENDIX D

Symbols and Messages

Table A: Hand-Held Remote Symbols and Messages

Table A explains the symbols and messages that appear on the Hand-Held Remote and its screen.

Symbol or Message	Description
	Stimulation on/off button
	Stimulation is on
OFF	Stimulation is off
+	Increase
-	Decrease
	Home (return to home screen)
	Full Rechargeable Battery
	Mostly full Rechargeable Battery
	Partially full Rechargeable Battery
	Low Rechargeable Battery; Replace and recharge
	Lock switch is off (buttons are enabled)
	Lock switch is on (buttons are disabled)
	Select Light Gray Lead (systems with 2 leads only)
	Select Dark Gray Lead (systems with 2 leads only)
Session Complete	The 6 hour therapy session is done
Wireless Error	BLUETOOTH® connection issue has occurred; See Appendix B
Lead Connect Error	A lead connection issue has occurred; See Appendix B
Internal Error	An issue has occurred; See Appendix B
Recharge Battery	Replace and recharge the Rechargeable Battery
Replace Remote Battery	Replace the Hand-Held Remote battery

Symbol or Message	Description
Con	Continue paused session (<i>Systems with 6 hour sessions only</i>)
New	Start new session (<i>Systems with 6 hour sessions only</i>)

Table B: Pulse Generator Lights and Tones

Table B explains the lights and tones that are output by the Pulse Generator.











Light or Tone	Description
Short beep 5 second Green light	Newly inserted Rechargeable Battery high to medium charge
Short beep 5 second Yellow light	Newly inserted Rechargeable Battery low charge
Short beep Flashing Yellow light	Newly inserted Rechargeable Battery critically low charge; Replace and recharge
Short beep Short Green light flash	Session started by press of Pulse Generator button
Single Blue light flash	Wireless command received
3 short beeps Flashing Yellow light	Stimulation stopped due to a low battery OR stimulation stopped due to an error OR internal error
Flashing Blue light	Pulse Generator is in BLUETOOTH® pairing mode

Table C: Label Symbols





Table C explains the symbols on products and packaging related to the SPRINT® PNS System. Not all symbols apply to the parts provided to you.

Symbol or Message	Description
REF	Model Number
Rx only	Restricted for sale by or on the order of a physician.

Appendix D: Symbols & Messages

Symbol or Message	Description
	Consult accompanying documents
	Caution: Consult accompanying documents
	Do not reuse
	Do not use if the product sterilization barrier or its packaging is compromised
STERILEEO	Sterilized using ethylene oxide
	Non-pyrogenic
LOT	Lot number
SN	Serial Number
 YYYY-MM-DD	Use by date (YYYY-MM-DD): This product should be used before the specified day.
	Keep dry
IP 22	The degree of protection from water and dust offered by the Pulse Generator. {unintentional and limited duration exposure to light rain}
MIN°C  MAX °C	Upper and Lower Limits of Temperature for shipping and storage
	Type BF applied part
	Manufacturing date

Appendix D: Symbols & Messages

Symbol or Message	Description
	Manufacturer
	MR Unsafe
	MR Conditional
	Not made with natural rubber latex

APPENDIX E

Contacting Customer Service

You should first attempt to contact your provider for any questions related to your SPRINT System. If you are unable to reach your provider, please contact Customer Service:

Via Mail:

SPR Therapeutics, Inc.
22901 Millcreek Blvd, Suite 110
Cleveland, OH, 44122 USA

Via Telephone:

Toll Free: 844-378-9108

Via Fax:

216-803-0777

Via Email:

support@sprtherapeutics.com

APPENDIX F

MRI Safety Information

The SPRINT System is MR Unsafe – All MRI procedures, no matter the anatomic site, are contraindicated for patients with the SPRINT System. Exposure can cause tissue heating and injury or unwanted stimulation. The MicroLead and all other System components should be removed from the patient before an MRI examination is performed. In the case of a MicroLead fracture beneath the skin resulting in a retained MicroLead fragment, an MRI examination is safe to perform under the conditions described in the MR Conditional statement below.




A retained MicroLead fragment ONLY is MR conditional – Non-clinical testing demonstrated that a retained MicroLead fragment entirely beneath the skin is MR conditional. A patient with a retained fragment can be scanned safely in an MR system under the following conditions:



- Static magnetic field of 1.5-Tesla only
- Maximum spatial gradient magnetic field of 1,000-Gauss/cm (10 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (Normal Operating Mode)

Under the scan conditions defined above, the fragment is expected to produce a maximum temperature rise of less than 3.3°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by a fragment extends less than 7mm from the fragment when imaged using a gradient echo pulse sequence and a 1.5-Tesla MR system.

 NOTE: There should be no section of MicroLead visible above the skin.

 NOTE: If a MicroLead is placed in an individual with an existing retained MicroLead fragment, the new MicroLead should not be placed in a location where it could touch the original MicroLead fragment. During MRI, two MicroLead fragments touching can result in an increase in temperature of the MicroLead fragments and surrounding tissue where they touch.

MRI Safety Card

Cut along the dotted line and carry this MRI safety card with you.

The SPRINT[®] PNS System is MR Unsafe – exposure to MRI can cause tissue heating and injury or unwanted stimulation.



A Retained MicroLead Fragment ONLY is MR Conditional – A person with a retained SPRINT[®] MicroLead fragment may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in tissue heating and injury as well as creation of an image artifact that obscures or prevents diagnoses.



Full MRI safety information is available in the MRI section of the product manual or can be obtained at www.SPRTherapeutics.com.



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