CURONIX

TRANSMITTER ASSEMBLY INSTRUCTIONS FOR USE FOR FREEDOM® NEUROSTIMULATION SYSTEMS

Caution: Federal law restricts this device to sale by or on the order of a physician.

TRANSMITTER ASSEMBLY KIT
PDBT-915-2K

WEARABLE ACCESSORIES
PNS Wearable Accessories:

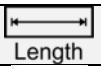
PNS Wearable Accessory L/XL Vertical 00-52002
PNS Wearable Accessory L/XL Horizontal 00-52003
PNS Wearable Accessory S/M 00-52004
PNS Wearable Accessory XXL Vertical 00-52036
PNS Wearable Accessory XXL Horizontal 00-52037

Torso Wearable Accessories:

Torso Wearable S 00-52013
Torso Wearable M 00-52014
Torso Wearable Size L 00-52015
Torso Wearable XL 00-52016
Torso Wearable XXL 00-52017
Torso Wearable XS 00-52018

EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE

Refer to the appropriate product for symbols that apply.

Symbol	English – EN
	Device reference identification
	Lot number
	Quantity of product included in package
	Prescription Only
	Consult instructions for use
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Store in a cool, dark, dry place
	Caution
	Warning
	MR Unsafe
	MR Conditional
	Use by
	Manufacturing date
	Manufacturer
	Device length
	Outer Diameter
	Sterilization: ethylene-oxide gas
	Double Sterile Barrier System

	Temperature limits
	Non-ionizing electromagnetic radiation
	IEC 60601-1/EN60601-1, Type BF Equipment
	Federal Communications Commission
	Dispose of this product according to local regulations
	Serial Number
	European Authorized Representative
	Swiss Authorized Representative
	CE Marking
	Importer
	Medical Device
	Unique Device Identifier

TABLE OF CONTENTS

GLOSSARY OF TERMS

Term and Synonyms	Definitions
Antenna	The antenna connects to the transmitter and transfers power and data from the transmitter, through the skin and to the implanted neurostimulator.
Caution	A statement describing actions that could result in damage to or improper functioning of a device.
Contraindication	A condition or circumstance that suggests or indicates that a particular technique or drug should not be used in the case in question.
Electromagnetic interference (EMI)	A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly
Neurostimulator (Stimulator)	Electrode Array(s) and connected Receiver(s)
PNS	Peripheral Nerve Stimulator implanted for pain relief
SCS	Spinal Cord Stimulator implanted for pain relief
Stimulation	The delivery of electrical pulses to the area where pain signals are blocked as they move to the brain. Stimulation blocks some pain signals from reaching the brain.
Transmitter Assembly	Transmitter Assembly. Describes the total assembly of a transmitter and antenna. The Transmitter Assembly is used in conjunction with the appropriate wearable accessory to apply therapy to the target nerve.

Transmitter	The transmitter is an external electronic device that generates wireless power and programs for the implanted neurostimulator. The transmitter contains buttons, a rechargeable battery, an antenna cable port, and a micro-USB port (for charging only).
Warning	A statement describing an action or situation that could harm the patient.

HOW TO USE THIS MANUAL

This manual provides instructions for the use and care of your neurostimulator system, including important warnings and precautions. Discuss with your clinician any questions or concerns you have after reading this manual.

FCC INFORMATION

FCC ID: 2AHXAPDBT2

This device complies with Part 18 of the FCC Rules. Per FCC 18.213, See Warnings section in this document for the interference potential of the device and methods for correcting interference. See Maintenance section in this document for the instructions on system maintenance.

Per FCC 15.21, changes or modifications to the device not expressly approved by Curonix LLC could void the FCC Certification and negate your authority to operate the equipment.

Per FCC 15.19(a)(3) and (a)(4) 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.

INDICATIONS FOR USE

FREEDOM SPINAL CORD STIMULATOR (SCS) SYSTEM

The Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.

FREEDOM PERIPHERAL NERVE STIMULATOR (PNS) SYSTEM

The Freedom Peripheral Nerve Stimulator (PNS) System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Freedom PNS System is not intended to treat pain in the craniofacial region.

SAFETY INFORMATION

CONTRAINDICATIONS

- **Poor surgical risks –** The Freedom SCS/PNS stimulators should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections, or other potential surgical risks as identified by the clinician. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.
- **Pregnancy –** Safety and effectiveness of the Freedom SCS/PNS System for use during pregnancy and nursing have not been established.
- **Inability to operate System –** The Freedom SCS/PNS Neurostimulation System should not be used on patients who are unable to understand or operate the System.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated near a patient implanted with a Freedom SCS/PNS System or when wearing the Transmitter Assembly. The energy from diathermy can be transferred through the Neurostimulator and cause tissue damage, resulting in severe injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Patients who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the device. The energy in high-level areas can be transferred through the device and cause tissue damage, resulting in severe injury. Examples of environments having high-level non-ionizing radiation include the following:
    - Radio or cell phone transmission stations
    - Facilities using radiofrequency heat sealers or induction heaters
    - Electric power infrastructure-controlled environments (i.e., step-down transformers or high-voltage power lines)
- **Implanted cardiac systems –** Patients with implanted cardiac systems should not use the Freedom SCS/PNS System. Electrical pulses from the device may interact with the sensing operation of an implanted cardiac system, causing inappropriate responses.

WARNINGS

Electromagnetic interference (EMI) – EMI is a field of energy generated by equipment found in the home, work, medical or public environments. A very strong EMI can interfere with the System. The device includes features that provide protection from EMI. Most electrical devices and magnets encountered on a normal day will not affect the operation of the System. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.
- Operational changes to the Transmitter Assembly. This may cause the external device to turn on, turn off, or to reset to the factory settings. If this occurs, the Transmitter Assembly needs to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation, that some patients have described it as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, patients have fallen and have been injured due to unexpected changes in stimulation.

Patients who suspect the Freedom PNS System is being affected by EMI should:

- Immediately move away from the equipment or object.
- The external Transmitter Assembly should be removed from the patient's vicinity.

Electromagnetic equipment/environments – Avoiding high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation.
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics.
- Industrial electric induction furnaces/heaters or electric arc furnaces/heaters used for melting metals and plastics.

- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment.
- Radio telemetry equipment used for tracking the location of vehicles, equipment, or animals.

Magnetic Resonance Imaging (MRI) – Freedom SCS/PNS Trial devices are MR Unsafe due to the lack of fixation of the device during the trial period.

Magnetic Resonance Imaging (MRI) – The Freedom SCS FR8A Electrode Array with connected Receiver are MR Conditional. An MRI examination with the Freedom SCS FR8A Electrode Array with connected Receiver may be safely performed under certain conditions.

Magnetic Resonance Imaging (MRI) – The Freedom SCS FR4A Electrode Array with connected Receiver is MR Unsafe. Since the Freedom SCS FR4A Electrode Arrays with Receiver is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the System, and in the process cause serious harm to the patient or other people or damage to the MR system.

Magnetic Resonance Imaging (MRI) – The Freedom PNS STQ4 and FR4A Electrode Array with connected Receiver are MR Conditional. An MRI examination with the Freedom PNS STQ4/FR4A Electrode Array with connected Receiver may be safely performed under certain conditions.

Magnetic Resonance Imaging (MRI) – The Freedom PNS FR8A Electrode Array with connected Receiver is MR Unsafe. Since the Freedom PNS FR8A Electrode Array with connected Receiver is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the System, and in the process cause serious harm to the patient or other people or damage to the MR system.

Magnetic Resonance Imaging (MRI) – <u>The Transmitter Assembly component is MR Unsafe; the Transmitter Assembly must not enter the MR system room</u>. Since the Transmitter Assembly is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the Transmitter Assembly, and in the process cause serious harm to the patient or other people or damage to the MR system.

Electrostatic Discharge (ESD) – Testing indicates the Transmitter Assembly can be susceptible to damage resulting from ESD greater than +/-6kV that can occur in certain environments, such as home use, when the relative humidity is below 30%. Freedom users and caregivers should avoid approaching or touching the Transmitter Assembly in these situations and avoid contact with highly charged surfaces, particularly synthetic materials (e.g., nylon, polyester) during periods of low relative humidity (less than 30%). ESD might result in temporary or permanent loss of function. If ESD with the Transmitter Assembly is observed, the device must be removed from the patient's body and powered off; then, the device can be powered on. Before resuming therapy, confirm the device indicators/lights are operating correctly. If the device does not power on, the stimulation therapy will not be delivered, and Curonix must be contacted for assistance or replacement.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a Neurostimulator. X-rays from the scan could cause unintended shocks or malfunctions of the Freedom SCS/PNS System.

The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the Transmitter Assembly from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
    - Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
    - Make sure that the X-ray beam does not dwell over the Freedom SCS/PNS System for more than a few seconds.

After CT scanning directly over the implanted device:

- The Transmitter Assembly can be placed back on the patient and stimulation turned on.
- Proper stimulation must be confirmed, and that indicator lights are operating as expected.
- The Transmitter Assembly must be shut off if it is suspected that the device is not functioning properly.

Radiation therapy – Safety has not been established for high radiation sources such as cobalt 60 or gamma radiation when implanted with the Freedom SCS/PNS System. The use of radiation therapy could cause damage to the device or harm to the patient.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with the Freedom SCS/PNS System. RF ablation may cause induced electrical currents that result in heating and tissue damage. RF ablation should not be used anywhere near the Freedom SCS/PNS System. If RF ablation is used, that ablation should not be performed over or near the Neurostimulator.

Radiofrequency Identification (RFID) Emitters – Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests have been performed with an array of simulated RFID emitter systems and have demonstrated that the Freedom SCS/PNS System (implanted device and Transmitter Assembly) can be affected by separation distances between the Freedom SCS/PNS System and the RFID emitter of less than 3m (~10 ft). More powerful RFID emitters might cause an effect at farther distances. RFID emitters can be hidden or portable and may not be obvious to the Curonix user. Any RFID emitter may temporarily interrupt stimulation and/or cause elevated levels of stimulation. It is recommended that if a patient feels a change in stimulation near a potential RFID emitter, they turn off the transmitter, promptly move away from the area and remove the Transmitter Assembly from their body. When possible, it is best to avoid RFID emitters or turn off and remove the Transmitter Assembly while passing near RFID emitters. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing any RFID emitter. If unavoidable, the patient should turn off the Transmitter Assembly, remove it from their body, then walk through the RFID emitter and promptly

move away from the area. Patients should not lean on scanners or linger in the area of RFID emitters.

Transcutaneous Electrical Nerve Stimulation – Safety has not been established for transcutaneous electrical nerve stimulation (TENS) when implanted with the Freedom SCS/PNS System. Use of TENS could cause the device to turn off or cause intermittently increased stimulation.

Electrocautery – Using electrocautery tools near the Freedom SCS/PNS System may cause damage to the insulation, causing the Freedom SCS/PNS System to potentially fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage.
When electrocautery is necessary, these precautions must be followed:

- The Transmitter Assembly should be removed from the vicinity of the patient.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
    - Only low-voltage modes should be used.
    - The lowest possible power setting should be used.
    - The current path (ground plate) should be kept as far away as possible from the Freedom SCS/PNS System.
    - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm the Freedom SCS/PNS System is working as intended.

High-Output Ultrasonics / Lithotripsy – Safety has not been established for high-output ultrasonics or lithotripsy when implanted with the Freedom SCS/PNS System. The use of lithotripsy may result in damage to the device or harm to the patient. When possible, it is best to avoid these security systems or to remove the Transmitter Assembly while passing through security systems. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing the security system. If unavoidable, the patient should walk through the security system and promptly move away from the area. Patients should not lean on scanners or linger around the security system.

Active Implantable or Body-Worn Medical Devices – Safety has not been established for patients who use the Freedom SCS/PNS System with other active implantable or body- worn medical devices. These devices include other neurostimulation systems, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system, harming to the patient or nearby people.

Bone Growth Stimulators – Safety has not been established for bone growth stimulator systems near the Freedom SCS/PNS System. Use of a bone growth stimulator may result in damage to the device or harm to the patient.

Dental Drills and Ultrasonic Probes – Safety for dental drills or ultrasonic probes near the Freedom SCS/PNS System has not been 15established. The use of drills or probes may result in damage to the device or harm to the patient.

Electrolysis – Safety has not been established for electrolysis near the Freedom SCS/PNS System. Use of electrolysis may result in damage to the device or harm to the patient.

Laser procedures – Safety has not been established for lasers near the Freedom SCS/PNS System. The use of lasers may result in damage to the device or harm to the patient.

Psychotherapeutic Procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients with the Freedom SCS/PNS System. Induced electrical currents can cause heating that may result in tissue damage.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet away from the implant site. Magnetic fields will generally not affect the Neurostimulator.

Machinery or Heavy Equipment – Machinery and heavy equipment (including vehicles) should not be operated while using the Freedom SCS/PNS System. A System malfunction could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the system.

Aircraft Usage – Safety has not been established for the use of the Freedom SCS/PNS System on aircrafts. Use of the Freedom SCS/PNS System on a commercial aircraft may result in damage to the device or harm to the patient.

Electrode Arrays Fracture – If the Neurostimulator insulation is ruptured or pierced due to excessive forces, unexpected changes in stimulation could occur.

Transmitter Assembly Skin Contact – The Transmitter Assembly and Accessories must not be placed directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The Transmitter Assembly must always be placed over a thin layer of clothing or material.

Painful Stimulation – If the patient experiences painful stimulation, decrease the power index and change to a lower amplitude program setting. If painful stimulation continues the Transmitter Assembly should be turned off.

Stimulation Frequencies – Stimulation between 1,500 Hz and 10,000 Hz has not been evaluated for safety, effectiveness, and perception of paresthesia in any Freedom SCS/PNS System. Specifically, for stimulation frequencies above 1,500 Hz, amplitudes that produce paresthesia have not been evaluated, and therefore, it is unknown whether injury may occur.

PRECAUTIONS

Physician Training – Prescribing clinicians should be experienced in diagnosing and treating chronic intractable pain and familiar with using the Freedom SCS/PNS System. Implanting clinicians should be experienced in spinal procedures, peripheral nerve procedures, and should review the Instructions for Use.

Medical Tests and Procedures – Before undergoing medical tests or procedures, patients should be instructed to contact the clinician to determine if the procedure could cause damage to the patient or the System.

Physician Instructions – Patients should be instructed to always follow the programs and therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Use the Transmitter Assembly as directed – Patients should be instructed to use the Transmitter Assembly only as instructed by the clinician and as discussed in this Instructions for Use. Use of the Transmitter Assembly in any other manner could result in harm. Use only the device and accessories directly from the Manufacturer; use of third-party accessories may damage the device and is prohibited.

Keep the Transmitter Assembly dry – The Transmitter Assembly is not waterproof. Patients should be instructed to keep it dry to avoid damage.

Clean the Transmitter Assembly – Patients should be instructed to clean the outside of the Transmitter Assembly with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device or labels.

Handle the Transmitter Assembly with care – The Transmitter Assembly is a sensitive electronic device. Patients should be instructed to avoid dropping the device onto hard surfaces and to keep the Transmitter Assembly out of the reach of children and pets.

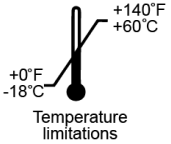
Do not dismantle the Transmitter Assembly – Patients should be instructed not to dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, a Curonix representative should be contacted for assistance.

Flammable or Explosive Environments – Patients should be instructed not to use the Transmitter Assembly in flammable or explosive environments. Using the Transmitter Assembly in one of these environments could result in harm.

Use of another patient's Transmitter Assembly – Patients should be instructed to never use another patient's Transmitter Assembly. The therapy program is a unique prescription for each patient. Use of another patient's Transmitter Assembly could result in overstimulation or decreased stimulation.

Storage Temperatures – The Transmitter Assembly should be kept within the storage temperatures listed on the product packaging. Exceeding the storage temperature could cause harm to the patient or the component. The manufacturer should be contacted if a storage temperature is surpassed.

Transmitter Assembly
Storage Temperature



Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. Before engaging in activities that could become unsafe, the System should be turned OFF. Discuss these activities with the clinician.

Interference during programming – If interference is suspected during the programming of the Transmitter Assembly, the clinician should confirm that the Bluetooth® data transmission is operating by ensuring the blue light indicator is blinking. If, during the programming session the light indicator is not blinking, then the clinician should do the following:

- Terminate current programming session.
- Check for sources of Bluetooth interference in the surrounding area.
- Remove or turn off the source of interference.
- Re-establish the Bluetooth® link with the Transmitter Assembly through pairing.
- Resume programming in the WaveCrest™ application.

- Confirm the light indicator is now blinking.

Activities requiring excessive twisting or stretching – Patients should be instructed to avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause the neurostimulator to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Scuba diving or hyperbaric chambers – Patients should be instructed not to dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Patients should discuss the effects of high pressure with the clinician before diving or using a hyperbaric chamber.

Skydiving, skiing, or hiking in the mountains – High altitude should not affect the System; however, undue stress on the Neurostimulator must be avoided. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the Neurostimulator. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Airline policies - Follow airline policies for using medical spinal cord or PNS stimulation systems and electronic equipment during flights. Refer all questions to airline personnel.

ADVERSE EVENTS SUMMARY

Implantation of a Neurostimulation system is similar to any surgical procedure. Patients should understand that risks include the following:

- Allergic or immune system response to implanted material
- Infection
- Leakage of cerebrospinal fluid
- Epidural hemorrhage, hematoma, bleeding, or paralysis

Therapeutic use of the Freedom SCS/PNS System incurs the following risks:

- Undesired change in stimulation, including uncomfortable chest wall stimulation

- Undesired change in stimulation, sometimes resulting in pain or muscle spasms
- Neurostimulator migration, erosion through the skin, or fracture leading to loss of therapeutic effect
- Electromagnetic interference leading to change in System performance
- Loss of therapeutic effect despite a functioning system

Adverse events that could occur with the Freedom SCS/PNS System:

- Neurostimulator migration, resulting in altered stimulation therapy that may be uncomfortable
- Neurostimulator fracture, resulting in loss of stimulation
- Infection, resulting in tissue sensitivity, redness, and swelling

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. The clinician must be contacted immediately if the patient experiences any problems. Patients should be instructed to contact their clinician immediately if they experience any problem or if they experience a change in stimulation. Over time there could be changes in the level of pain control. The clinician must be contacted if the patient experiences a change in stimulation that could be a result of the Neurostimulator migrating from the implant site.

DESCRIPTION OF YOUR NEUROSTIMULATION SYSTEM

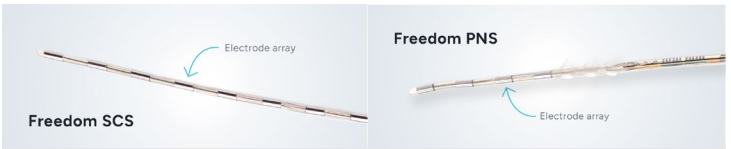
The Freedom neurostimulation system is composed of two parts: the implanted neurostimulator (**Freedom Stimulator**) that delivers the electrical pulses to block pain signals, and an external electronic device (**Transmitter Assembly**) used to power and control the neurostimulator.

Freedom Neurostimulator – The implanted neurostimulator is comprised of two components: an Electrode Array and a connected Receiver. The Transmitter Assembly transmits power to the Receiver, which connects to the Electrode Array to create an electrical field of energy. The electrical field delivered by the metal electrodes aids in blocking the pain signals coming from certain nerves near the spinal column or peripheral nerves.

Electrode Array

Freedom PNS 4-Contact Electrode with Tines

Freedom SCS 8-Contact Electrode without Tines



Receiver

Transmitter Assembly – The Transmitter Assembly is comprised of a transmitter and antenna. The Transmitter Assembly communicates with your neurostimulator by sending radiofrequency signals through the antenna. Your neurostimulator only accepts communication from your Transmitter Assembly

that is programmed by Curonix Representative with your specific stimulation parameters from an iPad wirelessly using Bluetooth.

Transmitter – The transmitter is an electronic device used to generate wireless power for the neurostimulator. The transmitter contains buttons, a rechargeable battery, an antenna cable port, and a micro-USB port (for charging only).

Antenna – The antenna emits wireless energy to the neurostimulator. The antenna connects to the transmitter with a cable. The antenna is worn externally, directly over, and parallel to the long axis of the Neurostimulator implant.

OVERVIEW OF THE USER CONTROLS

BUTTONS	
Key	**Action Description**
	**Increase Power Index Button** – Used to increase the radiofrequency energy to activate internal neurostimulator. . Holding the button down for more than 7 seconds ramps the power index to the highest level, 24.
	Power ON/OFF Button – Used to turn the Transmitter Assembly ON or OFF. Green LED is a default indicator and will blink to indicate power status.
	Decrease—Power Index Button – Used to decrease the radiofrequency energy. Holding the button down for more than 7 seconds decreases the power index to the lowest level, 1. A solid Yellow light indicates that the antenna is disconnected and is not functioning.
Change Program Selection – Depressing the Increase Button and the Decrease Button at the same time will alternate the programmed setting to either '1' to '2' to '3' and back to '1'.	

LEDS			
Action Description		**Pattern and Color**	**Description of Pattern**
	Charging		Solid Blue
	OFF, Not Charging		None
	Charge Complete Battery FULL		Blinking Blue
	Low Battery		Blinking Yellow
	ON Program Setting 1		Blinking Green (single)
	ON Program Setting 2		Blinking Green (double)
	ON Program Setting 3		Blinking Green (triple)
	Minimum Power Index		Blinks Once Yellow
	Maximum Power Index		Blinks Once Yellow
	Antenna Disconnected		Green is OFF Solid Yellow

POSITIONING THE TRANSMITTER ASSEMBLY

⚠ WARNING:

- Do not place the Transmitter Assembly directly on your skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The Transmitter Assembly must be placed over a layer of clothing at all times.
- Do not turn the Transmitter Assembly on without the antenna cable attached. Do not remove the antenna from the Transmitter Assembly during operation. This will damage the Transmitter Assembly.

Steps:

1. The antenna must be placed parallel and over the general region of the implanted Neurostimulator to transfer the optimal amount of energy. Adjust the physical position of the antenna up or down, or side-to-side, depending on where your neurostimulator is located.
2. The transmitter does not need to be placed over the neurostimulator, only the antenna. Your clinician and Curonix representative will assist you to find the optimal placement using the provided Wearable for effective therapeutic relief.
3. Affix the antenna to your body using the Curonix Wearable Accessory:
    a. Place antenna into antenna pocket of the Wearable Accessory.
    b. Align the cover with the face of the transmitter as shown in Figure **1** and snap into place.

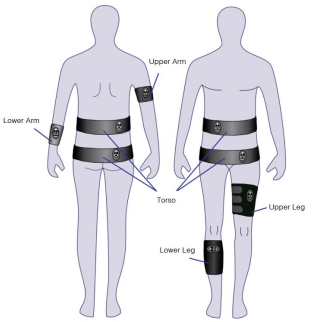
    c. Place transmitter into transmitter pocket of the Wearable Accessory.

d. Position the Wearable Accessory so that the antenna portion is over the region of the stimulator (reference Step 1).

4. Ensure that the Transmitter Assembly is placed over top of a thin layer of clothing. Do not place directly on your skin. Always place the antenna blue side outwards (away from the skin).

5. The system can tolerate antenna movements of 1.5 inches in any direction from center. If your antenna moves farther than 1.5 inches you may need to reposition the antenna over the implant area or adjust your stimulation amplitude.

6. Work with your clinician and Curonix representative to find the optimal location for the most effective therapeutic relief.



Freedom Systems Transmitter Assembly Positions using Curonix Wearables Accessories.
(Multiple locations shown for illustration purposes only)

CLIP PLACEMENT

Steps:

1. Prior to attaching clip:
    a. Alcohol wipe the back label and let dry for the best adhesion possible.
    b. Avoid touching clean surface with fingers after wiping the unit.
2. Attach the Adhesive Foam to the back side of the transmitter where the rectangle is on the label.

3. Remove the white 3M covering from the Adhesive Foam already placed on transmitter.
4. Attach Transmitter Clip to the Adhesive Foam as shown in Figure 2.

Figure 2

STARTING STIMULATION

TURNING THE TRANSMITTER ASSEMBLY "ON"

Notes:

- *TRANSMITTER ASSEMBLY automatically starts at lowest power setting (power index = 0) when turned on.*
- *Note: If program is changed, the power index automatically defaults back to power index = 0.*
- *The Transmitter Assembly should be loaded into the wearable and placed over the location of the internal neurostimulator before turning the transmitter on.*

Steps:

1. Turn the Transmitter Assembly ON by pressing the Power ON/OFF Key, the green Power Indicator Light will activate.
2. Adjust the power index as directed by your clinician by using the Increase or Decrease Key.

CHANGING A STIMULATION PROGRAM

The transmitter has three program options that may be set. The green indicator light is used to identify which program is currently active on the device. Your clinician and Curonix representative will instruct you on what program to use.

- Program 1 = Green Light Blinks ONE time
- Program 2 = Green Light Blinks TWO times
- Program 3 = Green Light Blinks THREE times

Steps:

1. After powered on, the transmitter defaults to the last program used.
2. Press  and  buttons at the same time and then release them to switch programs.
3. You will hear 1,2 or 3 'beeps', which will inform you that you are on program 1,2 or 3.
4. The light pattern will blink to signify which program is active; you will see the Power ON/OFF Key  flash 1, 2 or 3 times.

INCREASING OR DECREASING POWER INDEX

⚠ CAUTION:

Turn the power off or decrease the power index before changing the position of the Antenna to prevent possible uncomfortable stimulation.

Notes:

- *Transmitter Assembly must be turned on to increase or decrease the power index.*
- *The antenna component must be placed over the Stimulator to change the power index.*

Steps:

1. Press the  key to increase the power index.
2. Press the  key to decrease the power index.

Your clinician will provide guidelines about when you may want to adjust your stimulation. The following table provides general guidelines on how to adjust your stimulation.

Situation	Action
Stimulation is too strong	Option A: Lower the power index Option B: Change the program to a lower amplitude setting.
Stimulation is not strong enough	Change the program to a higher amplitude setting.
You have unexpected changes in stimulation	1. Turn the Transmitter Assembly off. 2. If the antenna moved, readjust it over the stimulator. 3. Turn the Transmitter Assembly on. 4. Turn on back to prescribed power index, if unexpected changes continue, keep device off and contact your clinician and Curonix representative.
You have tried adjusting stimulation but are unable to find an effective setting	Contact your clinician and Curonix representative.
You will be using potentially dangerous equipment	Turn off stimulation and remove the Transmitter Assembly from your body
You will be having a medical procedure	Notify the health care team of your implant. Turn off stimulation and remove the Transmitter Assembly from your body.

TRANSMITTER ASSEMBLY MAINTENANCE

BATTERY CHARGING

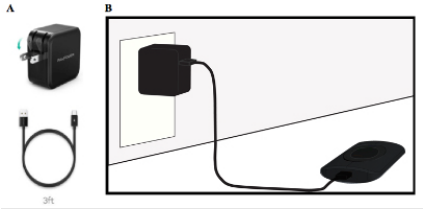
Notes:

- *Use only the USB Charger and cable provided to recharge the transmitter.*
- *Do not use the Transmitter Assembly USB Charger to charge other devices.*
- *To avoid damage to the USB Charging Port, ensure that the connectors are properly aligned.*

- *Do not remove the transmitter's built-in battery. Contact your clinician or Curonix representative if you are not experiencing optimal battery life.*
- *The Transmitter Assembly (antenna + transmitter) do not need to be connected during charging. It is recommended to keep the Transmitter Assembly together as one piece to avoid possible component damage.*
- *The transmitter cannot operate without the antenna connected. Operating the transmitter without the antenna connected will cause device damage.*
- *The transmitter will not charge when on.*
- *Do not charge the transmitter when in use.*
- *The transmitter does not need to be removed from the wearable during charging.*

Steps:

1. Turn the Transmitter Assembly off by pushing the Power ON/OFF Key  .
2. Remove the Transmitter Assembly from your body.
3. Connect the USB cable to the power adapter.
4. Plug the power adapter into a wall outlet.
5. Connect opposite end of USB cable to the micro-USB port on the Transmitter Assembly transmitter.
6. Charging Indicator Light  will stay solid blue on while the battery is charging.
7. Allow the battery to charge for at least four hours.
8. Charging Indicator Light  will blink blue when the battery is fully charged.
9. Transmitter Assembly is now ready to be used again.



Common Questions	Response
How long will it take to recharge the transmitter battery?	It normally takes an average of four (4) hours to recharge the battery. If the battery is drained to depletion, recharge time will increase.
When the transmitter battery is near depletion, and how will I know?	The yellow indicator light  will begin blinking. Eventually the Transmitter Assembly will turn off and not respond to user controls. You should connect the Transmitter Assembly to the charger as illustrated above.
What happens if I deplete the battery completely?	You cannot damage the Transmitter Assembly by running the battery completely empty. The device has safeguards to prevent this from harming the battery. Connect the Transmitter Assembly to the charger as described.
How long will a fully charged battery provide power?	Eight (8) hours on average. The battery performance is affected by the amount of total power used on average.
When is the battery done charging?	The battery is done charging when the Charging Indicator Light  (blue) blinks on/off.
Can I charge the Transmitter Assembly while the device is turned on?	No, you cannot charge the device while it is turned on. The stimulation cannot be used while the device is connected the charger.
Must I disconnect the device from the charger when full?	It is not necessary to disconnect the device from the charger when full.
Will the Transmitter Assembly feel warm during or after charging?	The Transmitter Assembly may feel warm during or immediately after charging.

TRANSMITTER ASSEMBLY CLEANING AND CARE PRECAUTIONS

Notes:

- *The device is not waterproof.*
- *Keep the device out of the reach of children and pets.*
- *Use the device only as explained to you by your clinician or as discussed in this manual.*
- *Handle the device with care. Do not drop, strike, or step on the device.*
- *Do not dismantle or tamper with the device.*

Steps:

1. Remove the Transmitter Assembly from your body.
2. Remove transmitter cover.
3. Clean the outside of the transmitter with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.

TRANSMITTER COVER CLEANING AND CARE PRECAUTIONS

Steps:

1. Remove the Transmitter Cover from the transmitter.
2. Use water, isopropyl alcohol, or a mild solution of warm water and dish detergent and a soft cloth to clean the surface. Do not use harsh solvents or ammonia-based products to clean the cover.

WEARABLE ACCESSORIES CARE INSTRUCTIONS

PNS Wearables Instructions:

Steps:

1. Remove all Transmitter Assembly components before washing.
2. Machine wash at cold setting; do not use high heat.
3. Hang dry or tumble dry at a low temperature.

Torso Wearables Instructions:

Steps:

1. Remove all Transmitter Assembly components before washing.
2. Hand wash only with cold water; Wash with mild detergent.
3. Air dry; Do not use bleach or other chemicals.

SAFETY AND TECHNICAL CHECKS

Periodic safety checks or maintenance of the Transmitter Assembly are not required. The Transmitter Assembly contains no user-serviceable parts. If repair or service is needed, contact your clinician or a Curonix representative for a replacement. Refer to the contact information at the end of this manual.

TRANSMITTER ASSEMBLY DISPOSAL

The Transmitter Assembly should be returned to your clinician or a Curonix representative. Do not dispose of your Transmitter Assembly in the garbage.

MEDICAL IMPLANT CARD

A Medical Implant Card is provided to you after Curonix receives your registration form. The Medical Implant Card supplies information about you, your stimulator system, and your doctor. Your Medical Implant Card may allow you to bypass security devices. Carry your Medical Implant Card with you at all times and bring this card with you to all MRI appointments. If you move, change doctors, or lose your card, contact Curonix for a replacement card. Refer to the Curonix contacts at the end of this manual.

POST-OPERATIVE CARE

During the two weeks following surgery, care must be taken to ensure that appropriate healing secures the implanted neurostimulator and closes the surgical incisions:

- Do not engage in rigorous physical activity such as twisting, bending, lifting heavy objects, or climbing.
- Do not remove or alter wound dressings without consulting clinical personnel.

- Continue to take any medications prescribed, such as antibiotics, unless otherwise directed by your clinician.
- Do not touch the wound or push, pull, or twist the implanted neurostimulator.
- Follow any other post-operative care instructions provided by your clinician.

Temporarily, you may experience some pain around the implant site as the incisions heals. If you experience significant pain, swelling, discharge, or excessive redness around the wound, contact your clinician. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

WHEN TO CALL YOUR CLINICIAN

Contact your clinician if any of the following events occur:

- You have pain, redness, or swelling later than 6 weeks after the implant procedure.
- The stimulation is causing you to have pain or discomfort.
- The system is not working properly.
- You cannot adjust stimulation using the user controls.
- You cannot place the Antenna in the optimal position to communicate with the stimulator.
- If you lose your Transmitter Assembly device.

Your clinician will schedule follow-up visits to make sure your device is working properly, and that the stimulation is managing your pain.

TRANSMITTER ASSEMBLY SPECIFICATIONS

Item	Specification
Amplitude	0 to 12.7 mA per electrode pair
Pulse Width	30 to 1000 µs
Pulse Frequency (of therapy)	5 to 1,499 Hz
Number of Programs (selectable)	3
Transmit Carrier Frequency	915 MHz
Bluetooth Frequency	2.402 GHz – 2.481 GHz
USB Charger Power Source	100-240V AC, 50/60 Hz power line
Operating/storage temperature, relative humidity	-18º C to 60º C (0º F to 140º F) 20% to 90%
Operating/storage atmospheric pressure	70 kPa to 150 kPa (20.7 in Hg to 44.3 in Hg)
Size (approximate)	7.6 cm x 5 cm x 2 cm (3 in x 2 in x 0.8 in)
Weight (approximate)	85 g (3 oz.)
Transmitter Enclosure Material (Product is to be worn over a thin layer of clothing at all times. Do not place directly on skin.)	Aluminum

WEARABLE ACCESSORIES

PNS Wearable Material Details:

Fabric is 75% Pa (Polyamide), 20% Ea (Elastomer), 5% PU (Polyurethane); Thread is 100% polyester; Velcro is HTH model made by Velcro brand.

The Curonix PNS Wearable Accessories are co-designed with Viviana Straps and use certified OEKO-TEX® hypoallergenic fabric and gripper. Manufactured by hand in Italy.

Torso Wearable Material Details:

Nylon / Polyacrylate (UBL) /Polyethylene (hook) / Polyester (Interfacing) / Velcro® Brand Hook 805.

Transmitter Cover Material Details:

Polycarbonate/ABS blend.

USB CHARGER SPECIFICATIONS

Parameter	Min	Typical	Max	Units
Supply Voltage	100	---	240	$V_{A/C}$
Supply Voltage Frequency	---	50 Hz or 60 Hz	---	Hz
Output Voltage (DC)	4.5	5	5.5	V
Output Power (total)	---	---	1	
Battery Recharge Time (assuming 3.7V battery)	--	5	--	hours

ELECTROMAGNETIC ENVIRONMENTS

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Freedom SCS and PNS System can be used in electromagnetic environments as specified below. The user of the System should assure that it is used in such an environment.		
Emissions Test	**Compliance level**	**Electromagnetic Environment – Guidance**
RF Emissions, CISPR 11	Group 1	Emits electromagnetic energy. Nearby electronic equipment may be affected.
RF Emissions, CISPR 11	Class B	System is suitable for use in all establishments, including domestic and those directly connected to public low-voltage power supply networks that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations, Flicker Emissions, IEC 61000-3-3	Class A	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 2kV contact +/- 4kV contact +/- 6kV contact +/- 8kV contact	+/- 2kV contact +/- 4kV contact +/- 6kV contact +/- 8kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
	+/- 2kV air +/- 4kV air +/- 8kV air +/-15kV air	+/- 2kV air +/- 4kV air +/- 8kV air +/-15kV air	
Electrical fast transient/ burst IEC 61000-4-4	+/- 2kV power supply lines +/- 1kV input/ output lines	+/- 2kV power supply lines +/- 1kV input/ output lines	Short Rise time, the repetition rate and low energy transients.
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	The major mechanisms by which lightning produces surge voltages are the following: a) A direct lightning strike to an external circuit (outdoor) injecting high currents producing voltages by either flowing through earth resistance or flowing through the impedance of the external circuit; b) An indirect lightning strike (i.e. a strike between or within clouds or to nearby objects which produces electromagnetic fields) that induces voltages/currents on the conductors outside and/or inside a building; c) Lightning earth current flow resulting from nearby direct-to-earth discharges coupling into the common earth paths of the earthing system of the installation.
Voltage dips, interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) 0.5 cycle 40% UT (60% dip in UT) 5 cycles	< 5% UT (> 95% dip in UT) 0.5 cycle 40% UT (60% dip in UT) 5 cycles	Voltage dips and short interruptions are caused by faults in the network, in installations or by a sudden large change of load. In certain cases, two or more consecutive dips or interruptions may occur. The

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
	70% UT (30% dip in UT) 25 cycles < 5% UT (>95% dip in UT) for 5s	70% UT (30% dip in UT) 25 cycles < 5% UT (>95% dip in UT) for 5s	continuously varying loads connected to the network cause voltage variations. The test shall be performed with the EUT connected to the test generator with the shortest power supply cable as specified by the EUT manufacturer.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 10 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF equipment should not be used closer to any part of the Freedom SCS System than recommended. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: UT is the AC mains voltage prior to application of the test level.

NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Freedom SCS/PNS System is used exceeds the applicable RF compliance level above, the Freedom SCS/PNS System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Freedom SCS System.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the Freedom SCS/PNS System

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

Rated Maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W).

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

WIRELESS INFORMATION

The Freedom SCS/PNS Systems use wireless technology to program the Transmitter Assembly and to power the Stimulator. The Transmitter Assembly is programmed utilizing Bluetooth® data communication protocol. Bluetooth is used only during programming sessions and only by a trained clinician. Various programs are stored in memory within the Transmitter Assembly, which can be selected as needed.

Transmitter Assembly Wireless Specifications	
FCC ID	2AHXAPDBT2
Transmission Frequency	915 megahertz (MHz)
Bandwidth	149 kilohertz (kHz)
Tissue Depth	Up to 6 cm
Quality of Service	In order for the Freedom SCS/PNS System to operate, Antenna is recommended to be placed over Neurostimulator within 0.8 inches or 2 cm to achieve optimal performance. Transmitter Assembly should be worn in the same position as when it was originally fitted. When the wireless link between the Transmitter Assembly and Stimulator is broken, stimulation will cease. The wireless link may not function in the presence of large magnetic or radio fields.
Bluetooth Version	4.1 (Low Energy Only)
Frequency of Bluetooth	2.4 gigahertz (GHz)
Bandwidth of Bluetooth	1 MHz
Power of Bluetooth	5.6 milliwatt (. milliwatt (W)
Bluetooth Operating Distance	4 to 5 meters
Wireless Link Performance	Wireless link active less than 10% of the time when Transmitter Assembly is 1 inch or closer to the implant.
Wireless Security	Stimulator will only operate within a short distance of Transmitter Assembly. The Transmitter Assembly uses encryption and proprietary data protocols to reduce the likelihood of inadvertent control or malicious “hacking” through Bluetooth®. Only the WaveCrest™ Application can communicate with the Transmitter Assembly via Bluetooth®. No identifiable personal data is stored or transmitted by the Transmitter Assembly.

Transmitter Assembly Wireless Specifications	
Bluetooth Quality of Service	Typical Bitrate: 360 bps Maximum Data Latency: 100 ms Maximum Operating Distance: 1 to 3 meters

TROUBLESHOOTING

NOTE:

- *If a problem is not solved after several attempts, or if a problem is not described here, contact your clinician and Curonix representative.*

This information can help you to solve problems that may arise with the Transmitter Assembly. It also provides information on when to call your clinician. The following table provides a systematic search for the source of a problem in order to solve it.

Problem	Causes and Actions
Uncomfortable stimulation: You are too uncomfortable with the current stimulation to think about how to change it.	Selected parameter settings are not suitable for your activity or posture. ▪ Turn of the Transmitter Assembly. ▪ Remove Transmitter Assembly from your body.
Intermittent stimulation: You feel stimulation only some of the time.	Option A: Lower the power index Option B: Change the program to a lower amplitude setting.
The Transmitter Assembly is unresponsive: The indicator light does not turn on. The power index keys do not respond.	The Transmitter Assembly is not powered on. ▪ Turn the power ON.  The Transmitter Assembly system has “frozen”. ▪ Turn the power OFF and wait 5 seconds before turning the power back ON. The battery is not charged. ▪ Recharge the battery by connecting the Transmitter Assembly to the charger.

Problem	Causes and Actions
Dropped Transmitter Assembly: Your Transmitter Assembly falls off a cabinet or table.	Transmitter Assembly is designed to withstand a short drop on a hard surface and still operate normally. If you receive a yellow blinking indictor warning light, turn it off and contact your physician and Curonix representative.
Fluid on the Transmitter Assembly: Substantial fluid was spilled onto the Transmitter Assembly, or the Transmitter Assembly was dropped into water.	The transmitter is IPX4 rated and can withstand only light splashes of water. The Transmitter Assembly is not waterproof, and submersion or significant exposure to water can damage the device.
Transmitter Assembly is heating up during operation.	The Transmitter Assembly will heat up during heavy operation and/or during use, just like your cell phone will be warm during heavy usage. Be sure to keep the Transmitter Assembly ventilated during operation; only the provided Wearable Accessory may be worn over it. Do not place the Transmitter Assembly directly on your skin. If the temperature becomes uncomfortable, power off, discontinue use, and remove the Transmitter Assembly. Contact your clinician and Curonix representative.

MRI Safety Information

Depending on the type of neurostimulator system that you have implanted, you may be safely scanned with magnetic resonance imaging (MRI) only under very specific conditions.

Inform the MRI Technician that you have an implanted neurostimulation system for chronic pain. The MRI safety information and product information can be found on the Medical Implant Card provided to you by Curonix. The MRI Safety Information and guidelines are also included in this user manual, or they can be found at www.curonix.com.

⚠ Warning:

Turn off and remove your Transmitter Assembly before entering the MR system room. The strong magnetic field of the MR system could attract or otherwise damage the unit and may cause serious harm or damage to the Transmitter Assembly and/or the MR system.

The MRI system technician can use the following information to obtain instructions to determine the eligibility of the Freedom Neurostimulation System (SCS/PNS) for the MRI procedure. Acceptable MR conditions to ensure patient safety can then be used.

MRI CONDITIONS FREEDOM SCS (FR8A) NEUROSTIMULATOR

Non-clinical testing demonstrated that the Freedom SCS (FR8A) Neurostimulator (Electrode Array with connected Receiver) is MR Conditional. A patient with the Freedom SCS (FR8A) Neurostimulator (Electrode Array with connected Receiver) can be safety scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Maximum spatial gradient magnetic field of 1000 Gauss/cm (10 T/m).
- Maximum MR system reported, whole body scans at 1.5-Tesla/64MHz, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).
- Torso Scans at 3-Tesla/128MHz - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg. This SAR limitation is more restrictive than the Normal Operating Mode.
- Head and Extremity Scans at 3-Tesla/128MHz – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).
- No other components of Freedom SCS System (e.g. Transmitter Assembly, battery charger, needles, stylets, guidewire, trial lead) may be taken into the MR system room.

Under the scan conditions defined above, the Freedom SCS (FR8A) Neurostimulator is expected to produce a maximum temperature rise of less than 4ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact extends approximately 20-mm relative to the size and shape of the device when imaged using a gradient echo pulse sequence and a 3-Tesla/128-MHz MRI system.

NOTE: *This information applies only to a single implanted Freedom SCS (FR8A) Neurostimulator (Electrode Array with connected Receiver).*

Magnetic Resonance Imaging (MRI) may be safely performed under specific conditions on a patient with the Freedom SCS (FR8A) Neurostimulator. In-vitro testing demonstrated that the Freedom SCS (FR8A) Neurostimulator are MR Conditional. The Freedom SCS (FR8A) System components are labeled as follows:

 MR Conditional Component	 MR Unsafe Components
Freedom SCS (FR8A) Neurostimulator (Electrode Arrays with Receiver) A patient with the Freedom SCS (FR8A) Neurostimulator (Electrode Array with connected Receiver) may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction.	• Freedom SCS (FR4A) Neurostimulator (Electrode Array with connected Receiver) • Freedom SCS (FR8A/FR4A) Trial Leads • Transmitter Assembly • Programmer • USB Battery Charger • Needle • Introducer • Guidewire • Steering Stylet

MRI CONDITIONS FREEDOM PNS (FR4A/STQ4) NEUROSTIMULATORS

Non-clinical testing demonstrated that the Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver) is MR Conditional. A patient with the Freedom PNS FR4A/STQ4 can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla.
- Maximum spatial gradient magnetic field of 1000 Gauss/cm (10 T/m).
- Neurostimulators/Leads Implanted in Upper Arm (e.g. located between elbow and shoulder):
  - Scanning the upper arm region (i.e. radial and ulnar nerves near the implant) at 1.5-Tesla/64MHz – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg. This SAR is more restrictive than Normal Operating Mode.
  - Scanning any other region (e.g. lower arm, shoulder, head, torso, leg) at 1.5-Tesla/64MHz – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).

- Neurostimulators/Leads Implanted in Lower Arm, Low Back, Pelvis, Leg:
  - Whole Body Scans (i.e. near or far from implant) at 1.5-Tesla/64MHz – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).
- No other components of Freedom PNS System (e.g. Transmitter Assembly, battery charger, needles, stylets, introducer assembly, trial lead) may be taken into the MR system room.

Under the scan conditions defined above, the Freedom PNS FR4A/STQ4 Electrode Array with connected Receiver are expected to produce a maximum temperature rise of less than 4ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 15 mm from the Freedom PNS FR4A/STQ4 Electrode Array with connected Receiver when imaged with a gradient echo pulse sequence and a 1.5-Tesla MRI system.

NOTE: *This information applies only to a single implanted Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver).*

Magnetic Resonance Imaging (MRI) may be safely performed under specific conditions on a patient with the Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver). In-vitro testing demonstrated that the Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver) is MR Conditional. The Freedom PNS System components are labeled as follows:

 MR Conditional Component	 MR Unsafe Components
Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver). A patient with the Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver) may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction.	• Freedom PNS (FR8A) Neurostimulator (Electrode Array with connected Receiver) • Freedom PNS (FR8A/FR4A) Trial Leads • Transmitter Assembly • Programmer • USB Battery Charger • Needle • Introducer • Guidewire • Steering Stylet

PREPARATION FOR AN MRI

The following steps are required prior to performing an MRI procedure on a patient who has an implanted Freedom SCS or PNS Neurostimulator System.

1. Remove the Transmitter Assembly (the external component of the System) from the patient before allowing the patient to enter the MR System.
2. Do not conduct an MRI procedure if the patient has any other implant or health condition that prohibits or contraindicates an MRI examination. If the patient has another implant, especially an electronically activated or "active" device, the safety of performing an MRI with the addition of Freedom Neurostimulator System (SCS/PNS) is unknown.
3. Instruct the patient to immediately inform the MR system operator (i.e., the MRI technologist) if any discomfort, stimulation, shocking, or heating, or other unusual sensation occurs during the examination.
4. The patient must be conscious during the MRI examination in order to inform the MR system operator of any problem.
5. Verify with the MR system operator that all proposed MRI conditions comply with the requirements specified in this manual. If any MRI parameter is not met and cannot be modified, do not perform the MRI procedure.

MR system operators that are unsure of the capabilities of the MRI system, must contact the MRI system manufacturer. If the MRI scan sequences do not meet the conditions, then the pulse parameters must be adjusted so that they comply.

DURING AN MRI EXAMINATION

The patient should be conscious during the MRI procedure. Monitor the patient both visually and audibly. Check the patient between each MR imaging sequence. Discontinue the MRI examination *immediately* if the patient is unable to respond to questions or reports any problem.

POST-MRI REVIEW

After the MRI procedure, verify that the patient feels normal. Verify that the Freedom Neurostimulator System SCS or PNS (Electrode Array with connected Receiver) is functional by checking its response to the Transmitter Assembly.

WARRANTY INFORMATION

Contact a Curonix representative for warranty information. Curonix contact information is provided in the last page of this Instructions for Use.

CONTACT INFORMATION

MANUFACTURER

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