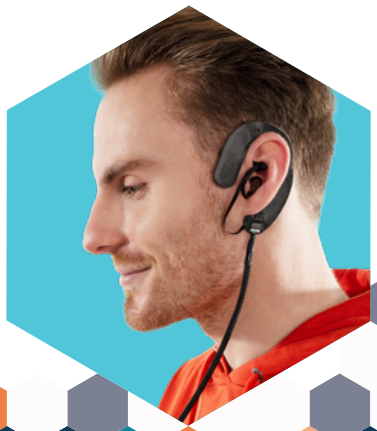
SPARROW™

Sparrow Therapy System™ Instructions for Use

(tAN™: Transcutaneous Auricular Neurostimulation)



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Rx ONLY **Caution: Rx Only. U.S. Federal Law restricts this device to sale by or on the order of a licensed healthcare provider.**

Indication for Use & Device Description

The Sparrow Therapy System is a wearable, battery-operated neurostimulation device intended to transcutaneously stimulate nerves in and/or around the ear. The Sparrow is a transcutaneous nerve field stimulator that is intended to be used in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel.

The Sparrow Therapy System is a single-use device intended for prescription use only as an aid to the standard of care. The patient undergoing therapeutic treatment should be under the care of a clinical professional trained in opioid reduction, detoxification, and/or recovery.

The system is designed to be worn up to 24 hours a day or as needed for relief of withdrawal symptoms. The disposable Earpiece should be changed daily, and the AA batteries powering the device should be replaced as needed, based on power consumption. The Sparrow Therapy System is provided non-sterile and should not be sterilized before use.

The Sparrow Therapy System is intended to be used only with the accessories described below:

Device Type	Model Number	Amount Included in Patient Kit
Patient Controller	100	1
Disposable Earpiece	200	7
48" Cable	848	1
AA batteries	N/A	15
Alcohol wipes	N/A	7

Sparrow Patient Controller – Model 100

The Sparrow Patient Controller is a hand-held, battery-powered device designed to be carried with the patient during therapy. The Patient Controller delivers stimulation to the Sparrow Earpiece via a removable Cable. The Patient Controller is powered by three standard Alkaline AA batteries.

The Patient Controller has a physical user interface composed of a 5-button membrane keypad that allows users to:

- Start and stop stimulation
- Adjust the stimulation intensity and
- Open an external Bluetooth connection to the clinician programmer.

In addition, the Patient Controller has four Light Emitting Diode (LED) lights indicating:

- Stimulation status
- Battery status
- Bluetooth connectivity status
- Disconnected Earpiece
- Impedance errors

The patient controller can be accessed via the Bluetooth-enabled Sparrow Clinician Application. The application allows healthcare providers to:

- Set the default stimulation parameters
- Retrieve and read the Sparrow Therapy System performance
- Retrieve and read the Sparrow Therapy System history logs

Button Functions

CENTER BUTTON

Wake from Sleep – Click the button once

Status Check – Click the button once. The LEDs lights will indicate system status

Unlock – Push and hold for 3-8 seconds until top light blinks white, then release

Return to Sleep Mode – Double click

CLINICIAN USE

Turn on Bluetooth – When unlocked, push and hold for 3-8 seconds until the top light blinks white, then release. In Bluetooth mode the bottom light also blinks blue.

Exit Bluetooth – Double click

ARROWS (Once Unlocked)

Turn Therapy On – Push both up arrows at the same time

Increase Therapy Intensity – Click the up arrow over the region shown

Decrease Therapy Intensity – Click the down arrow below the region shown

Turn Therapy Off – Push both down arrows at the same time

LIGHTS

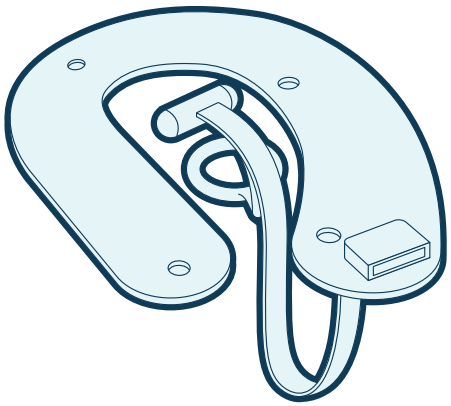
Top Light – Power and battery status
- Flashing Green Light: Ramping therapy
- Solid Green Light: Therapy is being delivered
- Solid Red: Out of battery power
- Solid Yellow: Low battery

Left Light – Region 1 therapy delivery status
- Solid Green: Therapy is being delivered
- Flashing Green: Ramping therapy

Right Light – Region 2 therapy delivery status
- Solid Green: Therapy is being delivered
- Flashing Green: Ramping therapy
- Alternating Left and Right Light: Therapy is in an OFF cycle as prescribed

Bottom Light – Connectivity status and errors
- Solid Red: Cable is disconnected
- Flashing Red: Earpiece is not properly connected to skin
- Flashing Blue: Bluetooth discovery mode
- Solid Blue: Bluetooth connected
- Flashing Yellow: Therapy cannot be increased due to high impedance

Sparrow Earpiece – Model 200

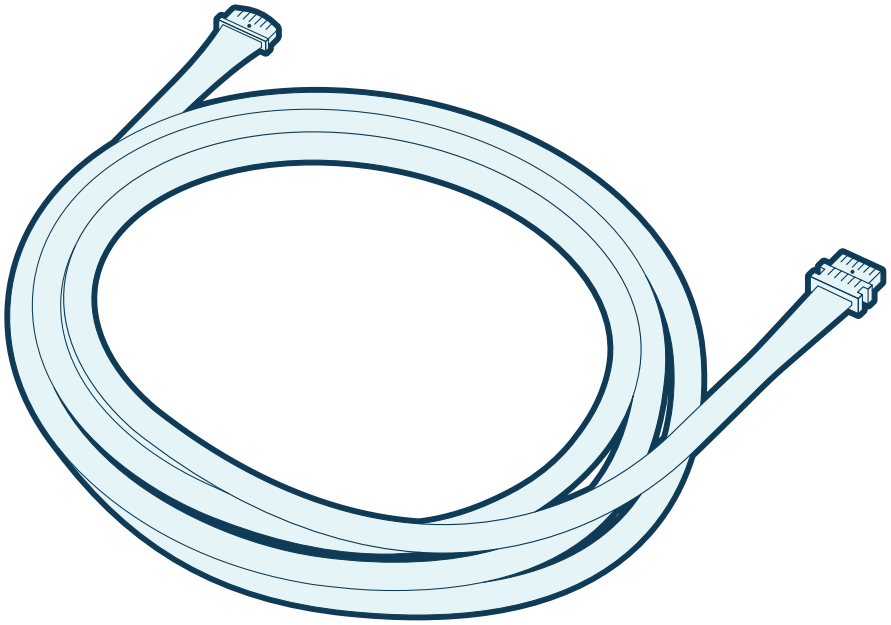


The Sparrow Earpiece is a wearable stimulation interface to be worn around the left ear for up to 24 hours. Both the outer and inner parts of the Earpiece are flexible, so that they can adjust to fit various sized ears. This disposable component of the Sparrow Therapy System is designed to stay adhered to the skin and provide electrical connectivity for up to 24 hours.

The Earpiece also has a connector port in which the user connects the Cable to receive electrical inputs from the Patient Controller.

Sparrow Cable – Model 848

The Sparrow Cable is 48 inches long and connects the Patient Controller to the Earpiece. It is designed to be long enough to enable the user to carry the Patient Controller in a pocket or worn on a belt without constricting mobility. The black end of the Cable connects to the Earpiece and the white end of the Cable connects to the Patient Controller. A black dot is located on the connectors to indicate connector orientation. Always insert the Cable to the Earpiece and Patient Controller with the black dot facing up.

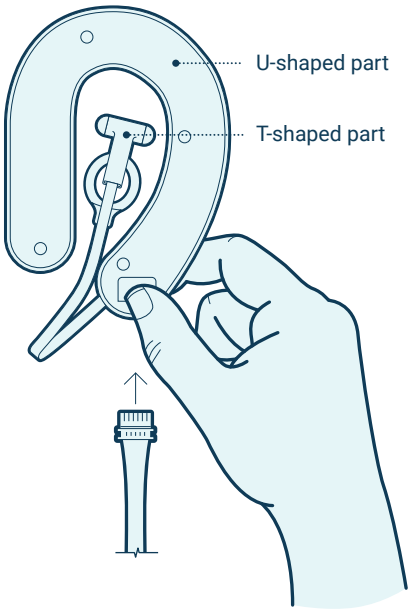


Directions for Use

Connect the Earpiece

1. Plug the narrow end of the 48" Cable into the bottom of the U-shaped Earpiece.

   CAUTION: Firmly hold the Earpiece connector with your index finger and thumb and insert the black end of the Cable with the black dot facing up. Do not bend or buckle the Earpiece when you insert the Cable. The Cable should insert easily; do not force.



Apply the Earpiece

2. Clean in and around the left ear with the alcohol wipe provided in the box to degrease the skin.

   NOTE: It may be necessary to shave the hair around the ear to reveal the skin (see Figure 1, Regions 2 and 3) to ensure there is no interference on the earpiece adhesion.

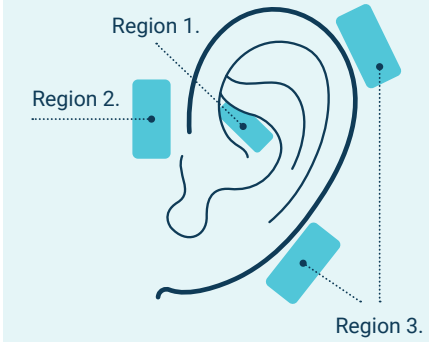
3. Remove the protective film covering the U-shaped part of the Earpiece and the T- shaped part of the insert, exposing both the adhesive and hydrogels.

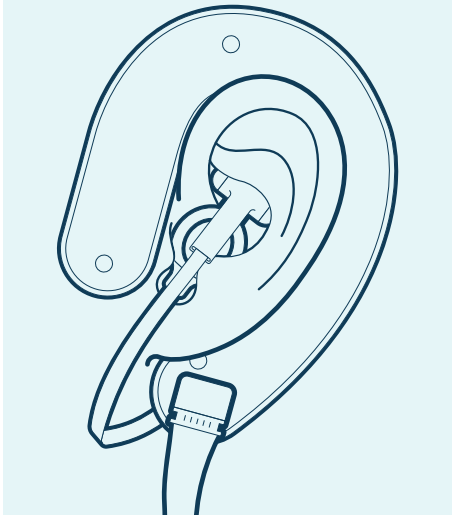
   NOTE: Try not to touch the hydrogels/adhesive surface.

4. Apply the U-shaped part of the Earpiece around the LEFT ear, making sure the entire Earpiece is making contact with the skin.

5. Place the T-shaped part of the insert within the center ridge, just above the ear canal (see Region 1). Then insert the O-shaped part just outside the ear canal. It should fit snugly to hold the T-shaped part in place.

Figure 1.





Use the Patient Controls

Be sure the Earpiece is connected and applied properly before using the Patient Controller. Connect the white end of the Cable to the Patient Controller.

NOTE: The clinician will program the device and customize the settings for the first use.

Patients can safely use the Sparrow Therapy System in the comfort of his/her own home and during most daily activities. Patients can turn the therapy on/off and adjust the stimulation intensity if necessary, by following the steps below.

6. Unlock the controller by holding the CENTER button 3-5 seconds until the top center light flashes white, then release. Do not release the center button until the white light is flashing. The top center light turns solid green once the Patient Controller is unlocked. The controller interface will lock after 30 seconds of inactivity, but therapy will continue.

7. Once ramping is complete, use the left and right UP/ DOWN buttons to adjust area 1 (Left) and area 2 (Right), respectively.

NOTE: If the clinician has not programmed stimulation parameters, press both the LEFT and RIGHT UP buttons simultaneously to turn stimulation on and enable adjustments.

To stop stimulation therapy, press and hold both DOWN arrows to turn all stimulation to 0.

The Patient Controller will automatically lower stimulation intensity when an high impedance event is detected. High impedance can be caused by an improperly cleaned ear, soiled Earpiece, re-used Earpiece, improperly fitted Earpiece, or unplugging the Cable while in use. See the trouble shooting section on page 12 to resolve.

It is typical to experience reduced or lost sensation of stimulation after prolonged use, however this does not mean the therapy will be less effective.

General Warnings and Cautions

General Warnings or Cautions in this User Manual are listed below and displayed in this document with the following WARNING or CAUTION symbols.

Example:

WARNING

CAUTION

Warnings

- If benefit is not established within 60 minutes of use, discontinue use and seek other methods of treatment.
- Do not service the Sparrow Therapy System devices while in use.
- Do not make any modifications to the Sparrow Therapy System devices.
- Only connect the Sparrow Therapy System to the approved components listed in this manual.
- The Sparrow 48" Cable may cause strangulation. Don't allow children to use or play with the Sparrow Therapy System.
- Do not use the Sparrow Therapy System with high-frequency surgical equipment.
- Do not use the Sparrow Therapy System near shortwave or microwave equipment.
- Do not use the Sparrow Therapy System in an explosive atmosphere or in the presence of flammable gas mixtures.
- Do not apply the Sparrow Earpiece on/near the thorax as it may increase the risk of fibrillation.
- Do not apply/use the Sparrow Earpiece in the presence of a wound, rash, swelling, cut, sore, drug patch, or surgical scar. This may result in discomfort, inadequate/inappropriate treatment, or decreased therapeutic response.
- Excessive hair around the ear may interfere with the ability of the Sparrow Earpiece to adhere to the skin and deliver therapy. Ensure the site is prepared in accordance with the directions in this manual for the best results.
- Always keep the AA batteries away from heat sources and fires.
- Stop using the product if you experience an allergic reaction while using the Earpiece and contact your physician.

Cautions

- Do not use the Sparrow Patient Controller in wet environments. Always keep the controller dry.
- Do not use contaminated, dirty, or previously used Sparrow Earpieces.
- Do not use other transcutaneous (e.g., TENS) or implanted neurostimulators while using the Sparrow Therapy System.
- Do not use the Sparrow Therapy System if any of the components are cracked, dented, or appear to be damaged.
- Do not use the Sparrow Earpiece if it has passed its expiration date indicated on the Earpiece Pouch.
- Do not use the Sparrow Earpiece if the protective covering is tampered with, damaged, or missing.
- Do not use the Sparrow System if the Sparrow 48" Cable is damaged.
- Do not clean the Sparrow Earpiece. Replace the Sparrow Earpiece if it is soiled.
- Do not use corrosive substances to clean the Sparrow Patient Controller or 48" Cable. Use only a clean, dry cloth to remove dust.
- Do not use soap, hand sanitizer, detergents, or other cleaners when cleaning the Sparrow Patient Controller or 48" Cable.
- Do not use the Sparrow Therapy System for greater than 6 hours continuously in high ambient temperatures (100°F). The Patient Controller device may reach temperatures of 43°C (109.4°F) which can be uncomfortable to touch.

Patient Safety

The Sparrow Therapy System meets the essential requirements of the European Medical Device Directive for General Product Safety and complies with the applicable U.S., Canadian, and other medical safety standards where the Sparrow Therapy System is registered to be sold.

Warnings

- Do not use the device beyond the safe limits of environmental conditions of temperature and humidity (see “Environmental Specifications” on page 14).
- Do no use the device in an MR environment.

Cautions

- **RF Interference** — The device conforms to ANSI/AAMI/EN/IEC 60601-1-2:2014; however, avoid environments with high levels of RF noise.
- **Other Interference** — The presence of an electrocautery device, infrared energy, or defibrillator may impact the operation of this device.
- Bluetooth function should be disabled prior to stimulation and remain disabled over the course of stimulation.
- Do not use the device in unintended areas.
- Do not use other devices in/on the ear at the same time as the Sparrow Therapy System.

Note

- **Electromagnetic Interference** — This device conforms to ANSI/AAMI/EN/IEC 60601-1-2:2014.
- **Biocompatibility** — All materials that come into contact with the user or patient are of the type commonly used in a clinical environment.

Troubleshooting

- **Bottom center light is blinking red** — The Earpiece may not be making connection with the skin. Gently press the Earpiece to the skin to improve adherence. If this does not fix the problem, change the Earpiece.
- **Bottom center light is solid red** — The system has lost connection with the Earpiece or Patient Controller. Check all Cable connections.
- **Bottom center light is blinking red/yellow** – The system had a high impedance event. To resolve, gently press the Earpiece to the skin to improve adherence before increasing stimulation. If this does not fix the problem, change the Earpiece.
- If you have any other questions, please contact Spark Biomedical, Inc. at (844) 654-SPRK (7775).

Maintenance, Cleaning, and Disposal

Maintenance

Changing the Earpiece

Earpieces are daily disposable and should be changed out every 24 hours. Prolonged use may cause damage to the skin. To change out the Earpiece, first stop simulation. Next, remove the Earpiece and unplug the Cable. Apply the new Earpiece following the steps on page 7.

Changing Batteries

Change the batteries on the Patient Controller as needed. The light on the top center of the device will turn red when the batteries are low. To change the batteries, first stop stimulation. Remove the battery cover on the back of the device, replace the batteries as noted on the illustration inside the cover, then close the cover. Turn the device back on using step 6 and turn stimulation back on to the programmed value using step 7.

NOTE: Changing the batteries does not affect the configured stimulation settings.

Cleaning

For both the Patient Controller and the Cable, use only a clean and dry cloth to remove dust as needed. Do not use corrosive substances to clean the Patient Controller or the Cable. Be sure the Patient Controller has been turned OFF before you start the cleaning.

The Earpiece is disposable and not intended to be cleaned or reused.

Cautions

- Do not clean Earpiece. Replace if soiled.
- Do not submerge the device in water; it is not water-resistant.
- Do not use soap, hand sanitizer, detergents, or other cleaners when cleaning the device.

Product Handling

Operating Conditions

- Range: 0° to 38°C (32° to 100° F)
- Humidity: 10% – 90%
- Barometric Pressure: less than 80 kPa
- Max Output Voltage: 95V
- Sparrow Therapy System produces an electrical signal consisting of a rectangular, symmetrical shaped waveform with 100 µs between phases. The waveform of the system pulse is biphasic.

Storage/Transport Conditions

- Make sure the device is turned OFF before storing.
- The Sparrow Therapy System should be stored at room temperature away from moisture.
- Range: 0° to 38°C (32° to 100°F)
- Humidity: 10% – 90%
- Barometric Pressure: less than 80 kPa
- Store device in such a way (e.g., drawer or shelf) that the device components are not damaged.
- Do not store the device in places where it could be subjected to vibrations or sudden impacts.

Service Life

The service life of the Sparrow Therapy System is one year after the date of manufacture.

Technical Details

Sparrow Patient Controller Device Specifications

Specification	Description
Dimensions (H X W X D)	137.8 x 63 x 72 mm (HxWxD)
Weight	5.5 oz. including battery
Disposal	According to WEEE: Directive 2012/19/EU – Device, accessories and packaging waste must be disposed of properly after each usage. Follow Local Ordinances and Regulations for disposal.
Service Life	1 year

Sparrow Earpiece Specifications

Specification	Description
Shelf Life	6 months
Weight	0.2 oz (1.5 oz with Cable)
Disposal	According to WEEE: Directive 2012/19/EU – Device, accessories, and packaging waste must be disposed of properly after each usage. Follow Local Ordinances and Regulations for disposal.

Electrical Specifications

Specification	Description
Power Supply	
Voltage	3 AA Alkaline Batteries (provided) in series, max 4.5V
Battery (new battery with a full charge)	
Capacity	Approximately 20 hours of normal use.

Environmental Specifications

Specification	Description
Temperature	
Operating	40°F to 100°F
Storage	40°F to 100°F
Fluid Rating	IP22 – protected against soft falling water, non-pressurized.

Stimulation Outputs

Amplitude, pulse width, and frequency meet or exceed IEC 60601-2-10:2016 requirements.

Amplitude Range	0 mA – 5.0 mA
Frequency Range	1 Hz – 150 Hz
Pulse Width Range	50 µs – 750 µs
Impedance Range	500 – 19,000 Ω

Configuration

Specification	Description
Bluetooth Low Energy (BLE)	
BLE Use Environment	The BLE wireless programming interface is intended to be used in medical office, industrial park, hospital, and home settings.
BLE QoS	BLE for stimulation programming should perform with <= 2s latency. If you experience slower communication performance, use the troubleshooting section to resolve. Contact Spark Biomedical if you are unable to resolve the BLE communication performance issues.
BLE Distance	Sparrow Patient Controller can safely be used around other wireless and cellular equipment. Standard BLE distances and line of sight requirements apply – a direct line of sight max distance is 10 m, obscured line of site max distance is 3 m.

BLE Use

The Sparrow Patient Controller offers wireless stimulation programming using Bluetooth Low Energy (BLE) from a mobile device. This interface sets the desired amplitude, pulse width, frequency, and cycle settings for the connected patient controller using the Sparrow Clinician App, Model 900.

Potential Issues with BLE Simulation Programming

In the event of extreme RF interference, you may experience delays in changes in EPG stimulation settings, or a disconnection of the Clinician Programmer from the EPG. When this occurs, the EPG will continue to use the last updated stimulation settings while BLE tries to resend the new settings. Note: The BLE transport protocol typically resolves these issues automatically without software or end-user action.

If you experience delays in programming performance, use the troubleshooting section to resolve. Contact Spark Biomedical if you are unable to resolve the BLE communication performance issues.

If you are unable to connect to the EPG device due to prolonged extreme RF interference, please contact Spark Biomedical to receive instructions on how to program the EPG without the Clinician Programmer

EMC Declarations

The Sparrow Patient Controller Device is intended for use in the electromagnetic environment specified below, which is representative of medical office, industrial park, hospital, and home settings.

Electromagnetic Emissions

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Sparrow Patient Controller Device is suitable for use in commercial, hospital, and typical home use environments.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A – primary cell powered	

Electronic Immunity

Immunity test	IEC 60601 test level	Compliance level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric Field Radiated IEC 61000-4-3	3 V/m from 80 MHz to 2700 MHz, 80% AM modulated, 1 kHz 9-28 V/m at Table 9 Frequencies	3 V/m from 80 MHz to 2700 MHz, 80% AM modulated, 1 kHz 9-28 V/m at Table 9 Frequencies	Angles and Sides: four angles (front, back, left and right) Antenna Distance: 3 meters (< 1 GHz); 1 meter (> 1 GHz)
Electrical fast transient/burst IEC 6100-4-4	---	---	N/A – primary cell powered
Surge IEC 61000-4-5	---	---	N/A – primary cell powered
Conducted Immunity IEC 61000-4-6	AC and SIP/SOP: 3 Vrms (6 Vrms in ISM Bands), 80% AM modulated, 1 kHz, from 0.15-80 MHz	AC and SIP/SOP: 3 Vrms (6 Vrms in ISM Bands), 80% AM modulated, 1 kHz, from 0.15-80 MHz	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	---	---	N/A – primary cell powered
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home use environment.
Conducted RF IEC 6100-4-6 Radiated RF IEC 6100-4-3	Vrms 150 kHz 80 MHZ3 V/m 80 MHz 2.7 GHz	3 Vrmsc3 V/mc	Portable and mobile RF communications equipment should be used no closer to any part of the Sparrow Patient Controller Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 √P d = 1.2 √P 80 MHz – 800 MHz d = 2.3 √P 800 MHz – 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey: A) should be less than the compliance level in each frequency range. Interference may occur in the vicinity of RF communications equipment

Immunity test	IEC 60601 test level	Compliance level	Compliance level
Note 1: The voltage is the main supply voltage, and the degradation is based on nominal voltage prior to the application of the test level. Note 2: 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 Sparrow Therapy System is used exceeds the applicable RF compliance level above, then the Sparrow Therapy System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sparrow Therapy System. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. c Amplitude modulated at 80% with a modulation frequency of 1 KHz per EN 60601-1-2			

Recommended Separation Distances

Refer to the following table for recommended separation distances between the Sparrow Therapy System and portable and mobile RF communication equipment.

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

Rated maximum output power of the transmitter W	Separation distance according to the frequency of the transmitter		
	150 kHz – 80 MHz d = 1.2 √P	80 MHz – 800 MHz d = 1.2 √P	800 MHz – 2.5 GHz d = 2.3 √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 estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer. Note 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.			

System Information

Symbols and Nomenclature Description

REF	Device Model Number and Name
	Manufacture Date
	Manufacturer
SN	Serial #
	FCC Symbol and ID
Rx ONLY	Prescription only
	Expiration date
	Follow instructions for use

	Storage temperature
	Disposal
	Caution
	Warning
	Applied part
	Note
	Single-Use

Clinical Study Summary

A double blind, randomized, prospective study, including a group with delayed treatment, was designed to assess the effectiveness of the Sparrow Therapy System. The study evaluated transcutaneous nerve stimulation (tAN) as a method to aid in the reduction of symptoms associated with opioid withdrawal.

The patient population included male and female participants, aged 18-65 with a history of dependence on prescriptive or non-prescriptive opioids (n=26). Subjects were enrolled at one US site based on 90% power at alpha 0.05 for detecting a mean (+SD) reduction in clinical opiate withdrawal scale (COWS) of 17 (+7) points when compared to baseline values.

In brief, study participants were randomized in a 1:1 ratio to one of two groups:

1. active transcutaneous auricular neurostimulation (tAN) + usual treatment or
2. delayed-active tAN + usual treatment

Participants in the active tAN group received tAN immediately whereas those in the delayed-active tAN had their therapy turned on after a delay (inactive period-first 30 minutes). All participants were informed of their group assignment at the conclusion of the randomized, double blind period and all continued to receive active tAN throughout the five-day study.

The primary effectiveness endpoint of this study was successful mean percent change in COWS score (defined as a ≥15% reduction) from baseline to 60 minutes after start of active tAN therapy.

The secondary endpoints of this study included:

- Comparison of mean percent change in COWS score in delayed active tAN versus active tAN groups at 30 minutes
- Comparison of the proportion of participants with a clinically significant reduction in COWS score (defined as a 15% or greater reduction) in delayed-active tAN versus active tAN groups at 30 minutes
- Mean percent change in COWS score from baseline to 30 minutes after start of active tAN therapy
- Mean percent change in COWS score from baseline to 120 minutes after start of active tAN therapy
- Mean percent change in COWS score from baseline to Days 2 through 5 after start of active tAN therapy

Safety Endpoints included the prevalence of all adverse events (AEs), serious adverse events (SAEs), adverse device events (ADEs), serious adverse device effects (SADEs), unanticipated serious adverse device effects (USADEs), and device deficiencies.

Of the 26 subjects enrolled in the study, 14 completed the study. The study results for all subjects including study completers and non-completers are listed below. Data from both the active tAN and the delayed-active tAN groups were pooled for the primary effectiveness analysis. The clinical study demonstrated that the subject device met the primary endpoint.

Key Metrics	All Subjects (N=26)	Study Completers (N=14)
Percentage of patients who passed the naloxone challenge[1]	10/ 26(38.5%)	10/14 (71.4%)
Percentage of patients completing the study	14/26 (53.8%)	---
COWS score percent reduction at 60 minutes	50.4%	50.5%
Percentage of patients transitioning to MAT	12/26 (46.2%)	7/14 (50.0%)

[1] The naloxone challenge was delivered if the subject UDS tested negative on Day 3 or Day 5. One subject did not pass the naloxone challenge at Day 3 and withdrew from the study. Among the 14 study completers, 10 completed the naloxone challenge, two on Day 3, and eight on Day 5. Four additional subjects did not participate in the challenge on Day 5 as they tested positive for opioids on the UDS and were no longer eligible due to risk of precipitated withdrawal.

Reasons for withdrawal from the study

The 12 subjects that did not complete the study had numerous reasons for early withdrawal. These reasons are listed below.

Reason	Number of Participants
Patients had a clinically meaningful reduction in COWS (symptom improvement) but decided to continue treatment with an opioid-based medication 1. Participant COWS score was reduced from a baseline score of 13 to a score of 4 at 60 minutes, 69.2% reduction. 2. Participant COWS score was reduced by 31.3% from a score of 16 at baseline to a score of 11 at 60 minutes.	2
Left detox facility against medical advice 1. One participant left with their partner (facility does not allow people who are dating to be together in the facility). Their COWS score was reduced from a 16 at baseline to an 8 at last assessment prior to leaving the facility, which was at 60 minutes (50% reduction). 2. One participant was withdrawn by the PI and was asked to leave because they left and brought heroin into the facility. Their COWS score was reduced from a 14 at baseline to a 7 at 60 minutes (50%reduction) and a score of 7 at 120 minutes, the last assessment prior to leaving the detox treatment facility. 3. Participant insisted on leaving treatment against medical advice due to high levels of cravings to use. Their COWS score was reduced from a 21 at baseline to a 10 at last assessment prior to leaving the detox treatment facility, which was at 60 minutes (52.4% reduction).	3
Subject broke patient controller	1
Frustration with use of device 1. Related to Bluetooth connectivity (Sparrow Therapy System application and firmware have resolved Bluetooth connectivity issue).	1
Device deficiency	1
Adverse Event (precipitated withdrawal due to naloxone challenge)	1
Non-responder to therapy	2
Protocol non-compliance 1. Subject was discovered with opioid based medication on Day 4 which broke protocol. Subject was removed from the study but not from the treatment facility. Subject tested negative for the opioid medication on Day 3.	1
TOTAL	**12**

Blinding

Results of the Patient Blinding Assessment showed that blinding was not able to be maintained despite adherence to all protocol procedures. This result is likely due to the initial perception of electrical stimulation during device programming, which provided a familiar sensation in line with the participant's expectation during active tAN.

Contact Information

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